APPENDIX A

HOSPITALS
INTERPRETIVE GUIDELINES
AND
SURVEY PROCEDURES

APPENDIX A

Interpretive Guidelines and Survey Procedures - Hospitals

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.2 Condition of Participation: Provision of emergency services by nonparticipating hospitals. (a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if-- (1) The services are emergency services; and (2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. See 42 CFR 405.152, 405.157, and 405.158 for provisions regarding emergency services. (b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) The statutory requirements that a hospital must meet are: o The hospital is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the injured, disabled, or sick persons. o The hospital maintains clinical records on all patients. o The hospital has medical staff bylaws. o The hospital has a requirement that every Medicare patient must be under the care of a physician.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) Document that the statutory requirements are met.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.2 Condition of Participation: Provision of emergency services by nonparticipating hospitals. (a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if-- (1) The services are emergency services; and (2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. See 42 CFR 405.152, 405.157, and 405.158 for provisions regarding emergency services. (b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) The statutory requirements that a hospital must meet are: o The hospital is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the injured, disabled, or sick persons. o The hospital maintains clinical records on all patients. o The hospital has medical staff bylaws. o The hospital has a requirement that every Medicare patient must be under the care of a physician.	§482.2 Condition of Participation: Provision of emergency services nonparticipating hospitals. (2) Document that the statutory requirements are met.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	o The hospital provides 24-hour nursing services rendered or supervised by a registered professional nurse, and has a licensed, practical or registered professional nurse on duty at all times. o The hospital is licensed or is approved as meeting the standards for licensing as a hospital as defined by the State.	
§482.11 Condition of Participation: Compliance with Federal, State and local laws.	§482.11 Condition of Participation: Compliance with Federal, State, local laws.	§482.11 Condition of Participation: Compliance with Federal, State, local laws.
(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.	Self-explanatory	(a) Interview the CEO to determine whether the hospital is in compliance with Federal laws related to patient health and safety. (E.g., if the hospital has been convicted of violating section504 of the Rehabilitation Act of1973 by denying handicapped persons access to care, verify that satisfactory corrections have been made to bring the hospital into compliance with that law.)
(b) The hospital must be --		(b) Prior to the survey, determine whether the hospital is subject to licensure requirements and verify that the licensing agency has approved the hospital as meeting the standards for licensure.the agency of the State or locality responsible for licensing hospitals.
(1) Licensed; or		
(2) Approved as meeting standards for licensing established by		
(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.		(c) Verify for those personnel required to be licensed by the State, that the hospital has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Check a random sample of personnel files to verify that licensure information is up to date.
§482.12 Condition of Participation: Governing body. The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this Part that pertain to the governing body.	§482.12 Condition of Participation: Governing body. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.	§482.12 Condition of Participation: Governing body. Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.
(a) Standard: Medical staff. The must --		(a) Standard: Medical staff. governing body
(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;		(1) Verify that all practitioners are licensed in compliance with State laws.
(2) Appoint members of the medical staff after considering the recommendations of the existing members of of the medical staff;	(2) It is the responsibility of the governing body to determine with the advice of the medical staff, the categories of practitioners appointed to the medical staff.	(2) Evaluate records of medical staff appointments to substantiate the governing body's involvement in appointments of medical staff members. Confirm that the governing body appoints all members to the medical staff in accordance established policies and based on the practitioners scope of the clinical expertise.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A020	(3) Assure that the medical staff has bylaws.	Survey Procedures: §482.12(a)(3)&(4) Verify that the medical staff operates under current bylaws, rules and regulations that have been approved by the governing body. Verify that any revisions or modifications in the medical staff bylaws, rules and regulations have been approved by the medical staff and governing body, e.g., bylaws are annotated with date of last review and initialed by person(s) responsible.
A021	(4) Approve medical staff bylaws and other medical staff rules and regulations.	
A022	(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.	Interpretive Guidelines: §482.12(a)(5) Verify that the governing body is periodically apprised concerning medical staff evaluation of patient care services provided in the institution. Survey Procedures: §482.12(a)(5) Verify that any individual providing patient care services is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.
A023	(6) Ensure that criteria for selection are individual character, competence, training, experience, and judgement; and	Interpretive Guidelines: §482.12(a)(6)&(7) A hospital is not prohibited from requiring board certification when considering a physician for medical staff membership. Rather, the regulation provides that a hospital may not rely solely on the fact that a physician is or not board certified in making a judgement on medical staff membership. In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence and judgement. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff. Survey Procedures: §482.12(a)(6)&(7) Verify that there are written criteria for staff appointments, and that these criteria are character, competence, training, experience, and judgement, and are not dependent solely upon certification, fellowship, or membership in a specialty body or society.
A024	(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A025	(b) Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.	Survey Procedures: §482.12(b) Verify that the hospital has a chief executive officer appointed by the governing body.
A026	(c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met: (1) Every Medicare patient is under the care of:	Interpretive Guidelines: §482.12(c)(1) Practitioners other than doctors of medicine or osteopathy may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with State law. Survey Procedures: §482.12(c)(1) Verify that Medicare patients are under the care of a licensed practitioner as defined by (c)(1).
A027	(i) A doctor of medicine or osteopathy (this provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism); (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;	

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State, but only with respect to services related to the condition of aphakia; or

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manipulation of the spine to correct a sublaxation demonstrated by x-ray to exist.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by

the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, the patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(2) Verify that admitting privileges are limited to those categories of the State Law

(3) Verify the governing body has established and monitors the enforcement of policies that ensure a doctor of medicine or osteopathy is on duty or on call at all times to providemedical care and onsite supervision when necessary.

NOTE: See comment on A-6.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		Review the "call" register and obtain documents which assure that a doctor of medicine or osteopathy is on duty or on call at all times. If emergency room services are provided, determine that coverage is provided for that service.
(4) A doctor of medicine or osteopathy is responsible for full responsibility the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice, as defined by the medical staff and permitted by State law and as limited by paragraphs (c)(1)(iv) and (v) of this section, of any of the practitioners specified in paragraphs (c)(1)(ii) through (v) of this section.		(4) Verify that a doctor of medicine monitors the osteopathy assumes for the care of each Medicare patient with respect to all medical or psychiatric problems during the hospitalization.
(5) (i) To identify potential organ donors as defined in '485. 302 of this chapter, the hospital has written protocols that:		
(A) Assure that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;		(A) Verify that the hospital has policies that include: o Written criteria to identify potential organ donors: o Protocols regarding which categories of staff may notify family members of their options; o A requirement for immediate acceptance of a family's decision to decline the option to donate organs.
(B) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors;		(B) Review the hospital's training plan for those staff persons designated by the hospital to notify the family of its options. Assure that the training plan encourages discretion and sensitivity when notifying the family of its options. Verify that the training plan stresses acceptance and respect of each individual's circumstances, views and beliefs.

NOTE: See comment on A-6.

(C) Require that an organ procurement organization designated by the Secretary under §85.308 of this chapter be notified of potential organ donors

(C) Verify by review of policies and records that the Organ Procurement Organization (OPO) is notified as soon as possible of a potential organ donor. Confirm that the OPO is designated by the Secretary. Ask the hospital for the name, address, and telephone number of the OPO.

(ii) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation Network established under section 372 of the Public Health Services Act and must abide by its rules and requirements.

(ii) If the hospital performs transplants verify that it is a member of the Organ Procurement and Network. (Exhibit 4-168). If the hospital is not on the list, call the regional office to determine if it has recently become a member.

(iii) For purposes of this subparagraph the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(d) Standard: Institutional plan and budget.
The institution must have an overall institutional plan that meets the following conditions:

(d) Standard: Institutional plan and budget. Do not review the specifics or format in the institutional plan or the budget, but verify that:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(1) An institutional plan and budget exists; and includes items (d) 1-4 of the regulation.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following.

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See Part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because-- (i) The facilities do not provide common services at the same site; (ii) The facilities are not available under a contract of reasonable duration; (iii) Full and equal medical staff privileges in the facilities are not available;		(5) Determine that the hospital's plan for capital expenditures has been submitted to the planning agency designated to review capital expenditures. In certain cases facilities used by HMO and CMP patients are exempt from the review process.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(iv) Arrangements with these facilities are not administratively feasible; or		
(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.		
(6) The plan must be reviewed and updated annually.		(6) Verify that the plan and budget are reviewed and updated annually.
(7) The plan must be prepared--		(7) Verify that the governing body and administrative and medical staffs have participated in the development of both.
(i) Under the direction of the governing body; and		
(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.		
(e) Standard:Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.	(e) Standard:Contracted services. The governing body has the responsibility for assuring that hospital services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by arrangement.	(e) Standard:Contracted services. Ascertain that all contractor services provided in the hospital are in compliance with the Conditions of Participation for hospitals.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.	(1) Indirect arrangements may take into consideration services provided through formal contracts, joint ventures, informal agreements, shared services, or lease arrangements. The patient care services provided under contract are subject to the same hospital-wide quality assurance evaluation as other services provided directly by the hospital.	(1) If the services provided under arrangement relate to patient health and safety, review the quality assurance plan to ensure that the service is evaluated.
(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.		(2) Review the list of contracted services and verify that there is a delineation of contractor responsibility.
(f) Standard: Emergency services.		(f) Standard: Emergency services.
(1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.		
(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.		(2) Verify that the medical staff has adopted written policies and procedures for the management of medical or psychiatric emergencies.

REGULATIONS

§482.21 Condition of Participation: Quality assurance (QA).

The governing body must ensure that there is an effective, hospital-wide QA program to evaluate the provision provision of patient care.

INTERPRETIVE GUIDELINES

§482.2 Condition of Participation Quality assurance (QA).

The condition requires that each hospital develop its own QA program to meet its needs. The methods used by each hospital for self-assessment (QA) are flexible. There are a wide variety of techniques used by hospitals to gather information to be monitored. These may include document-based review (e.g., review of medical records, computer profile data, continuous monitors, patient care indicators or screens, incident reports, etc.); direct observation of clinical performance and of operating systems and interviews with patients and/or staff. The information gathered by the hospital should be based on criteria and/or measures generated by the medical and professional/technical staffs and reflect hospital practice patterns, staff performance, and patient outcomes.

SURVEY PROCEDURES

§482.21 Condition of Participation: Quality assurance (QA).

Survey of the QA condition should be coordinated by one surveyor. However, each surveyor should review the quality assurance plan. Each surveyor as he/she surveys the other conditions should determine if there is evidence of monitoring and evaluation of that condition. A hospital that continually evaluates the quality of care generally provides high quality patient care. A hospital-wide QA program should focus on the objective and systematic monitoring and evaluations of the quality and appropriateness of patient care, efforts to improve patient care and identification and resolution of patient care problems.

Interview the staff person(s) responsible for managing the QA program. Items for discussion include:

- Description of the organization of the QA program and its method of operation including its accountability to the governing body.
- How does the medical staff monitor clinical performance?
- How is the quality and appropriateness of patient care monitored and evaluated?
- How are hospital policies and clinical privileges revised based on QA?

Use the following sources to determine if the hospital's QA program monitors and evaluates all major areas of patient care.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Readmissions o Medical records evaluation reports o Incident reports o Infection contact report o Blood utilization reports o Pharmacy reports or drug usage review o Medication errors o Laboratory, radiology, and other diagnostic clinical reports - e.g., repeat testing o Committee/department reports o Surgical case review/tissue review reports o Medical and surgical services review -for appropriateness of diagnosis and treatment o Use of experimental drugs and procedures (method of approval) o Patient/staff complaints o Evaluation of the granting of clinical privileges - e.g., must be commensurate with the individuals documented training experience and current competence o Reappraisal/reappointment of medical staff o Utilization review o Appropriateness of discharge
(a) Standard: Clinical plan. The organized hospital-wide QA program must be ongoing and have a written plan of implementation.	(a) Standard: Clinical plan. Ongoing means that there is a continuous and periodic collection and assessment of data concerning the important aspects of patient care. Assessment of such data enable areas of potential problems to be identified and indicates additional data which should be collected and assessed in order to identify whether a problem exists. The QA program must provide the hospital with findings regarding quality of care. The QA plan should include at least the following:	(a) Standard: Clinical plan. Review the hospital's written QA plan. Verify that the hospital's QA plan includes the elements specified in the interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	o Program objectives o Organization involved o Hospital-wide in scope o All patient care disciplines involved o Description of how the program will be administered and coordinated o Methodology for monitoring and evaluating the quality care o Ongoing o Setting of priorities for resolution of problems o Monitoring to determine effectiveness of action o Oversight responsibility-reports to governing body o Documentation of the review of its own QA plan	
(1) All organized services related to patient care including services furnished by a contractor, must be evaluated.	(1) "All organized services" means all services provided to patients by staff accountable to the hospital through employment or contract. All patient care services furnished under contract must be evaluated as though they were provided by hospital staff. This means that all patient services must be evaluated as part of the QA program, that is: o Dietetic services o Medical records o Medical staff care-appropriateness and quality of diagnosis and treatment o Laboratory service o Nursing service o Pharmaceutical service o Radiology service o Hospital wide functions	(1) Determine that the scope of the QA program includes an evaluation of all services provided directly or under arrangement (including the services of the medical staff). To avoid duplication of effort and assure adequate attention to problems of the hospital, determine that mechanisms are in place to assure appropriate communication across departments and services.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	- Infection control - Utilization review (for hospitals under PRO review this requirement does not apply) - Discharge planning program If the hospital offers these optional services, they must also be evaluated: o Anesthesia services o Emergency services o Nuclear medicine services o Outpatient services o Psychiatric services o Rehabilitation services o Respiratory services o Surgical services Each department or service should address: o Patient care problems o Cause of problems o Documented corrective actions o Monitoring or follow-up to determine effectiveness of actions taken.	
(2) Nosocomial infections and medication therapy must be evaluated.		(2) Determine that nosocomial infections and medication herapy are evaluated by the hospital. These are hospital-wide functions and may be evaluated as such.
(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.	(3) All services provided in the hospital must be periodically evaluated to determine whether an acceptable level of quality is provided. The services provided by each practitioner with hospital privileges must be periodically evaluated to determine whether that are of an acceptable level of quality and appropriateness.	(3) Determine that the hospital is monitoring patient care in-cluding clinical performance. Determine that a review of medical records is conducted and that the records contain sufficient data to support the diagnosis and to determine that the procedures are appropriate to the diagnosis.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A055	(b) Standard: Medically-related patient care services. The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients.	Survey Procedures: §482.21(b) Review the hospital's plan for providing or making available timely services to meet the medically-related social work, psychological and educational needs of its patients. Where the services are to be provided by other than hospital staff, review the documentation of the agreements (e.g., contracts, memorandum of understanding, or letters of agreement) to assure that services are available to all patients needing them.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A058	(c) Standard: Implementation. The hospital must take and document appropriate remedial action to address deficiencies found through the QA program. The hospital must document the outcome of the remedial action.	Survey Procedures: §482.21(c) Determine if the hospital has taken appropriate action to correct problems identified by the QA program. Examine reports and minutes of meetings to determine that the hospital has documented the remedial action and its outcome. Examples of appropriate remedial action may include, but are not limited to: o Changes in policies and procedures; o Staffing and assignment changes; o Appropriate education and training; o Adjustments in clinical privileges; o Changes in equipment or physical plant; and o Review and revisions of a plan itself. Opportunities to improve care should be applied on a hospital-wide basis, when appropriate. Verify that the hospital takes and documents remedial action when problems are identified and that the outcome of these actions are evaluated. The results must be transmitted to the governing body to fulfill its responsibility to ensure an effective QA program.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A059	§482.22 Condition of Participation: Medical Staff The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.	
A060	(a) Standard: Composition of the Medical Staff The medical staff must be composed of doctors of medicine, osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.	Survey Procedures: §482.22(a) Determine that the medical staff has a mechanism that is used to periodically appraise its current members and their qualifications in accordance with State law requirements. The medical staff must also define what is periodic appraisal. The purpose of the appraisal is to determine the suitability of members in order to maintain membership on the medical staff and to justify the continuation of clinical privileges.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A061	(1) The medical staff must periodically conduct appraisals of its members.	Interpretive Guidelines: §482.22(a)(1) The medical staff appraisal procedures must evaluate training, experience, and demonstrated competence of a member established by the hospital QA program, and the member's adherence to medical staff bylaws and rules and regulations. Survey Procedures: §482.22(a)(1) Verify that an outcome-oriented appraisal system is conducted for all members of the medical staff.
A062	(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.	Survey Procedures: §482.22(a)(2) Verify that there is a mechanism established to examine credentials of prospective members by the medical staff. The credentials examined include at least: o A request for clinical privileges; o Current licensure; o Training and professional education; o Documented experience; and o Supporting references of competence. Verify that the medical staff makes recommendations to the governing body for new members that are specific to type of appointment and extent of clinical privileges, and that the governing body takes final appropriate action. (A separate credentials file should be maintained for each medical staff member or applicant.)
A063	(b) Standard: Medical staff organization and accountability. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.	

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) The medical staff must be organized in a manner approved by the governing body.		(1) Verify if the medical staff has a formalized organizational structure, that lines of function and responsibility are delineated between the governing body and other parts of the organization, and that the governing body has sanctioned its approval on the organizational structure and relationships.
(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.		(2) Verify, if there is an active executive committee that a majority of the members are doctors of medicine or osteopathy.
(3) The responsibility for organization and conduct of medical staff must be assigned only to an individual doctor of medicine or osteopathy.		(3) Verify from the organizational structure and through conversations with members of the medical staff that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff.
(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:	(c) Standard: Medical staff bylaws.	(c) Standard: Medical staff bylaws. Verify that the bylaws describe a mechanism for ensuring enforcement of its provisions along with rules and regulations of the hospital.
(1) Be approved by the governing body.	(1) The medical staff must regulate itself by bylaws and rules and regulations that are consistent with acceptable medical staff practices. The bylaws must be enforced and revised as necessary.	(1) The surveyor must verify the existence of current and complete medical staff bylaws long with rules and regulations which have been approved by the governing body.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)		(2) Verify that the bylaws specify the role and responsibilities of each category of practitioner on medical staff.
(3) Describe the organization of the medical staff.	(3) The bylaws must describe the organizational structure of the medical staff, and lay out the rules and regulations of the medical staff to make clear what are acceptable standards of patient care for all diagnostic, medical, and surgical and rehabilitative services.	(3) Verify that the bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body. Verify that the bylaws describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff and describe the formation of leadership in the medical staff.
(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.	(4) The governing body has the prerogative to determine which categories of licensed practitioners are eligible for appointment to the medical staff, qualified in accordance with State law.	(4) Verify that the bylaws describe the qualifications such as licensure, specific training, experience, current competence and health status to be met by a candidate for appointment by the medical staff.
(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.		(5) Determine that the bylaws require a physical examination and medical history be done for each patient by a M.D. or D.O. or where appropriate, an oromaxillofacial surgeon, no more than 7 days before or 48 hours after admission. (The MD/DO may delegate all or part of the physical examination and medical history to other practitioners, but the MD/DO must sign for and assume full responsibility for these activities.)

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.		(6) Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to various categories of the medical staff and that a procedure exists for applying these criteria.
(d) Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.		(d) Standard: Autopsies. Verify that the medical staff has policies requiring the practitioners to attempt to secure permission to perform autopsies, that the mechanism for documenting permission to perform an autopsy is defined, and that there is a system for notifying the medical staff, specifically the attending practitioner, when an autopsy is performed.
§482.23 Condition of Participation: Nursing Services. The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.	§482.23 Condition of Participation: Nursing Services. Self-explanatory.	§482.23 Condition of Participation: Nursing Services. Interview the director of the service. Request the following items: o Organization chart(s) o Job or position descriptions including the director's o Staffing schedules for the last complete week for each unit o Nursing service policies and procedures manuals Tour the nursing units and observe the nursing care in progress to determine the adequacy of staffing and the delivery of care. Other sources of information to use in the evaluation of the nursing services are:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Nursing care plan o Medical records o Patients o Accident and investigative reports
(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.		(a) Standard: Organization. Review the organizational chart or plan for nursing services. Determine that the organizational chart(s) displays lines of authority that delegates responsibility within the department. o Read the position description for the director of nursing (DON) to determine that it delegates to the DON specific duties and responsibilities for operation of the service. o Verify that the director is currently licensed in accordance with state licensure requirements. o The organization will include various configurations of the following personnel as determined necessary by the hospital and the Director of Nursing: + Assistant/Associate Director(s) + Supervisors/Coordinators + Head Nurses/Nurse Managers + Staff Nurses + Unit Secretaries/Clerks + Nurses Aide/Order lies

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.	(b) Standard: Staffing and delivery of care. The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being served.	(b) Standard: Staffing and delivery of care. Determine that there are written staffing schedules which correlate to the number and acuity of patients. Staffing schedules must be reviewed and revised as necessary to meet the patient load and to make adjustments for nursing staff absenteeism. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration: o Physical lay out and size of the hospital. o Number of patients o Intensity of illness and nursing needs. o Availability of nurses aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc. o Training and experience of personnel. o Do not count personnel assigned to areas other than bedside patient care.
(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or a registered nurse on duty at all times, except for rural hospitals that have in effect a 24-		(1) Review the nurse staffing schedule for a week prior to the survey. If you find insufficient nurse coverage, examine the schedule for a second week to determine a pattern of insufficient coverage. Document daily RN coverage for every ward or

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
hour nursing waiver granted under §405.1910(c) of this chapter.		unit of the hospital. Use the format in the survey report form. Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Bear in mind that 4 1/2 FTE RNs are required to meet the requirement of the standard for a small hospital. Additional nurses may be required for vacation or absenteeism coverage.
	Exception: §405.1910(a)(b) and (c) sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24-hour registered nurse requirement by the regional office. Rural is defined as all areas not delineated as "urbanized" areas by the Census Bureau, in the most recent census. Temporary is defined as a one year period or less and the waiver cannot be renewed.	Exceptions: Document the following: o 50 or fewer inpatient beds o The character and seriousness of the deficiencies do not adversely affect the health and safety of patients. o The hospital meets all the other statutory requirements in section 1861(e)(1)-(8). That is, the hospital: (a) Is primarily engaged in providing to patients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. (b) Maintains clinical records on all patients. Has bylaws in effect with respect to its staff of physicians. (c) Has medical staff bylaws.

(d) Has a requirement that every patient is under the care of a physician.

(e) Has in effect a hospital utilization review plan.

(f) Is licensed or meets standards for licensing pursuant to State and local law.

(g) Has in effect an overall institutional plan and budget for an annual operating budget and a capital expenditure plan.

- The hospital has made and continues to make a good faith effort to comply with the 24-hour nursing requirement. Determine the recruitment efforts and methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies. Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.

- The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

- A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week.

- On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.		(2) Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses.
(3) A registered nurse must supervise and evaluate the nursing care for each patient.		(3) Determine that an RN is assigned to supervise and evaluate the nursing care furnished to each patient.
(4) The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient.		(4) Select a sample of nursing care plans. Approximately 6-12 plans should be reviewed. o Are they initiated as soon as possible after admission for each patient? o Do they describe patient goals and as appropriate physiological and psychosocial factors and patient discharge planning? o Is each plan in consonance with the attending physicians plan for medical care? o Are they revised as the needs of the patient changes? o Are the plans implemented?

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.		(5) Review the nursing assignments. Were the assignments made by a RN? Determine that the assignments take into consideration the complexity of patient's care needs and the competence and specialized qualifications of the nursing staff. Ask a charge nurse what considerations are necessary when making staff assignments. Answers should include: o Patient needs o Job abilities of personnel o Education of personnel o Location of patients o Workload balance
(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.		(6) Review the method for orienting non-employee licensed nurses to hospital policies and procedures The orientation should include at least the following: o The hospital and the unit o Emergency procedures o Nursing services policies/ procedures If the hospital uses non-employee licensed nurses, are they supervised by an RN who is a regular employee of the hospital? Confirm with the director of nurses that a non-employee nurse's performance is evaluated by the hospital at least once a year. If the performance evaluation is not considered confidential, review two evaluations.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State law, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. (1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.		(c) Standard: Preparation and administration of drugs. (1) Ascertain that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration: o Ascertain that there are policies and procedures approved by the medical staff covering who is authorized to accept telephone or verbal orders, who is authorized to administer medications, and that the policies are followed. o Review a sample of medication administration records to see that they conform with the practitioner's order, that the order is current, and that drug and dosage are correct and administered as ordered.

- Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Patient should be addressed by name and/or identiband should be checked. The nurse must remain with the patient until medication is taken. Determine that drugs are administered within 60 minutes of the scheduled time for administration.

- Verify that nursing or other personnel authorized by medical staff policy to administer drugs have completed appropriate training courses or are licensed or authorized to do so by State law and function under supervision as necessary.

- Check the quality assurance activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors, their nature, frequency and the corrective action taken.

- Interview supervisory nursing personnel to determine the method of providing supervision. Also question personnel who administer medication to verify that the supervision is, in fact, provided.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioner(s) responsible for the care of the patient as specified under §482.12(c). When telephone or oral orders must be used, they must be:		(2) Determine that all drug orders are written in the patient charts and signed by the practitioner caring for the patient.
		o Read the hospital's policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?
(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;	Most State laws require that telephone or verbal orders be signed by the prescribing practitioner within 48 hours.	o Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized hospital personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so. Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.
(ii) Signed or initialed by the prescribing practitioner as soon as possible; and		
(iii) Used infrequently.		

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.		(3) Review the transfusions and intravenous medications practices: o Are blood transfusions and IVs administered in accordance with State law and approved hospital policies and procedures. Review a sample of medical records to determine that only doctors of medicine or osteopathy or specially trained personnel perform this duty. If the nursing service trains personnel for IV administration, look at the content of the inservice course. It should include: - Fluid and electrolyte balance - Blood components - Venipuncture techniques, demonstrations and supervised practice.
(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.		(4) Request the hospital procedure for reporting adverse drug reactions and errors and transfusion reactions. Review the incident reports or other documentation that the procedure is being implemented and regularly monitored through quality assurance activities.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.24 Condition of Participation: Medical record services.	§482.24 Condition of Participation: Medical record services.	§82.24 Condition of Participation: Medical record services.
The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.		Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the hospital and the patients.
(a) Standard: Organization and staffing.		(a) Standard: Organization and staffing.
The organization of the medical record service must be appropriate to the scope and complexity of the service performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.		Verify that there is an established system which addresses at least the following activities of the medical records services: o Timely processing of records o Coding/indexing of records o Retrieval of records o Protecting the confidentiality of medical information o Compiling and retrieval of data of quality assurance activities Verify that the system is reviewed and revised as needed. Review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.
(b) Standard: Form and retention of record.		(b) Standard: Form and retention of record.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.		Verify that a medical record is maintained for each person receiving care. (A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced.) Verify that written procedures ensure the integrity of authentication and protect the security of patient records. Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.
(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.	(1) Medical records are retained in their original or legally reproduced form in hard copy, microfilm, or computer memory banks.	(1) Determine that records are retained for at least 5 years, or more if required by State or local laws.
(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.		(2) Verify that the hospital uses a coding and indexing system that permits timely retrieval of patient records by diagnosis and procedure.
(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records must be		(3) Verify that only authorized persons are permitted access to records maintained by the medical records department.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
released only to authorized individuals and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.		Verify that the hospital has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., physician responsible for patients care) determines that direct access is not likely to have an adverse effect on the patient. Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or as dictated by hospital policy. Verify that copies of medical records are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes. Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.
(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.		(c) Standard: Content of record. Review a sample of active and closed records for completeness and accuracy in accordance with hospital policy. The sample should be ten percent of the census, but not fewer than 30 records.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A102	(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.	Interpretive Guidelines: §482.24(c)(1) (1) Entries in the medical record may be made only by individuals as specified in hospital and medical staff policies. All entries in the medical record must be dated and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code. When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the hospital a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The parts of the medical record that are the responsibility of the physician must be authenticated by this individual. When non-physicians have been approved for such duties as taking medical histories or documenting aspects of physician examination, such information shall be appropriately authenticated by the responsible physician. Any entries in the medical record by house staff or non-physicians that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication. Any system that would meet the authentication requirements are as follows: o Computerized systems which require the physician to review the document on-line and indicate that it has been approved by entering a computer code. o A system in which the physician signs off against a list of entries which must be verified in the individual record. o A mail system in which transcripts are sent to the physician for review, then he/she signs and returns a postcard identifying the record and verifying their accuracy. A system of auto-authentication in which a physician or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.
A103	(i) The author of each entry must be identified and authenticate his or her entry.	
A104	(ii) Authentication may include signatures, written initials, or computer entry.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Survey Procedures: §482.24(c)(1) Verify that entries are authenticated; Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification. Verify that computer or other code signatures are authorized by the hospital's governing body and that a list of these codes is maintained under adequate safeguards by the hospital administration. Verify that the hospital's policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes. Examine the hospital's policies and procedures for using the system, and determine if documents are being authenticated after transcription.
A105	(2) All records must document the following, as appropriate.	Survey Procedures: §482.24(c)(2) Verify that the patient's medical record contains documentation of a physical examination performed within the required time period. Verify that the patient records contain the following information: o Admitting diagnosis; o Consultation report documented as required by medical staff policy; o Reports of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia; o Properly executed consent forms containing at least the following: -- Name of patient, and when appropriate, patient's legal guardian; -- Name of hospital
A106	(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.	
A107	(ii) Admitting Diagnosis	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A108	(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.	-- Name of procedure(s) -- Name of practitioner(s); -- Signature of patient or legal guardian; -- Date and time consent is obtained; -- Statement that procedure was explained to patient or guardian; and -- Signature of professional person witnessing the consent.
A109	(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.	
A110	(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law, if applicable, to require written patient consent.	

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.		Verify that the patient records contain appropriate documentation of practitioners' orders, notes and reports and other information needed to monitor the patients condition.
(vii) Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.		Verify that a discharge summary is included to assure that proper continuity of care is required. For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for followup care.
(viii) Final diagnosis with completion of medical records within 30 days following discharge.		Make sure that a final diagnosis is included in the discharge summary.
§482.25 Condition of Participation Pharmaceutical services.	§482.25 Condition of Participation Pharmaceutical services.	§482.25 Condition of Participation: Pharmaceuticals services.
The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.		Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.		Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.
(a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.	(a) Standard: Pharmacy management and administration Standards of practice as defined by State law must be followed regarding the provision of pharmaceutical service. The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems. properly stored.	(a) Standard: Pharmacy management and administration Determine that professional principles are maintained by verifying that: o Policies and procedures have been developed and are being followed. o Drugs and biologicals are o Records have sufficient detail to follow the flow of control from entry through dispensation. o Employees provide pharmaceutical services within the scope of license and education. Inspect the adequacy of controls over drugs and medications including the floor stock and those of the pharmacy or drug room. Review the pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies. Determine that drugs are being dispensed only by a licensed pharmacist. Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals by:

- Reviewing policies and procedures.
- Interviewing pharmacy and hospital staff to determine how drugs and biologicals are dispensed.
- Observing onsite dispensing operations (if applicable).
- Reviewing records of drugs and biologicals removed from the pharmacy by nonpharmacy personnel.
- Inspecting drug storage areas.
- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
- There are inspections of drug storage areas throughout the hospital.
- There is a drug recall procedure.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(1) Direction of pharmaceutical services may not require on premises supervision but may be accomplished through regularly scheduled visits.

(1) Document whether the pharmacist is a full-time, or part-time employee or employed on a consultative basis.

Review the implementation of the chief pharmacist's responsibilities by examining:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Written status reports o Minutes of meetings (if any) with facility staff regarding pharmaceutical services o Schedules, time logs, etc. Review the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services.
(2) The pharmaceutical services must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.	(2) There are sufficient personnel to respond to the pharmaceutical needs of the patient population being served.	(2) Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7 day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.
(3) Current and accurate records must be kept on the receipt and disposition of all scheduled drugs.		(3) Determine if there is a record system in place that provides the information on controlled substances in a readily retrievable manner. Review the records to determine that they trace the movement of scheduled drugs throughout the service. Determine that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.		(b) Standard: Delivery of services. Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.		(1) Verify through interviews of pharmacy and hospital staff, observation of onsite dispensing operations and review of pharmacy records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws.
(2) Drugs and biologicals must be kept in a locked storage area.		(2) Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.
(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.		(3) Spot check the label of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information: o Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Each floor stock container bears the name and strength of the drug, lot and control number or equivalent, expiration date. If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.		(4) Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.
(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is pre-determined by the medical staff.		(5) Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue or review patients' medication administration records to determine compliance with stop-order policy.
(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.		(6) Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.		(7) Interview the pharmacists, or pharmacy employees to determine their understanding of the controlled drug policies. Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for. Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
(8) Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage indications for use, and routes of administration must be available to the professional staff.	The facility has immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug and with nursing personnel selection and with nursing personnel to assist in the identification of drug induced problems.	(8) Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current. Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulatory, how to resolve drug therapy problems, and other general information as the need arises.
(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.		(9) Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.26 Condition of participation: Radiologic services. The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. (a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients. (b) Standard: Safety for patients, and personnel. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel. (1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.	§482.26 Condition of participation: Radiologic services. Diagnostic radiology services provided under contract may be provided either on the hospital premises or in an adjacent, readily accessible facility.	§482.26 Condition of participation: Radiologic services. When services are provided in an adjacent facility, apply the condition of participation to the adjacent facility as if it were a part of the hospital itself. (a) Standard: Radiologic services. Verify that the hospital maintains, or has available, organized and directed radiologic services that meet the needs of the patients and accepted professional standards of practice. (b) Standard: Safety for patients and personnel. Verify that the hospital has adopted policies and procedures to provide safety for patients and personnel. (1) Verify that these hospital policies contain safety standards for at least: - Adequate shielding for patients, personnel and facilities. - Appropriate storage, use and disposal of radioactive materials.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.		(2) Verify that there is a policy requiring periodic inspection. Review record to verify that the inspections are conducted and that any hazards identified are promptly corrected.
(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.		(3) Verify that there is a policy for periodic checks. Review records to verify that periodic tests of radiologic personnel by exposure meters or test badges are performed.
(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.		(4) Verify that the hospital has policies that radiologic services are provided on the order of practitioners with clinical privileges and to practitioners outside the hospital where authorized by the medical staff and governing body and permitted by State law.
(c) Standard: Personnel.		(c) Standard: Personnel.
(1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologic's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.		(1) Verify that a qualified radiologist interprets the tests designated by the medical staff to require a radiologist's knowledge. o Determine that the medical staff established the qualifications of the the radiologist for appointment to the medical staff. o Examine the radiologist's credentials to verify that he/she meets the qualifications established by the medical staff for appointment. (If not, cross-refer deficiency back to δ482.22(a)).

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES

- o Verify through an examination of the records, observation of the radiologist service and interviews with radiologic staff, the nature and extent of supervision.
- o Verify that supervision of the radiologic services is restricted to a radiologist who is a member of the medical staff. Supervision includes, but is not limited to the following:
  - + Enforcing safety standards;
  - + Ensuring that radiologic reports are signed by the practitioner who interpreted them;
  - + Assigning duties to radiologic service personnel commensurate with their training, experience, and licensure if applicable;
  - + Enforcing infection control standards;
  - + Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A138		Survey Procedures: §482.26(c)(1) + Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and + Training radiology staff on how to operate the equipment safely, carry out tests offered by the facility and on the management of emergency radiation hazards and accidents.
A139	(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.	Survey Procedures: §482.26(c)(2) Examine hospital policies and personnel folders to verify that radiologic personnel meet the qualifications established by the medical staff.
A140	(d) Standard: Records. Records of radiologic services must be maintained.	Survey Procedures: §482.26(d) Observe the procedures for maintaining radiologic records to determine that: (1) Reports are signed by the practitioner who reads and evaluates the roentgenogram. (2) Verify that the hospital maintains records for at least 5 years.
A141	(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.	
A142	(2) The hospital must maintain the following for at least five years:	
A143	(i) Copies of reports and printouts.	
A144	(ii) Films, scans, and other image records, as appropriate.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A145	§482.27 Condition of Participation: Laboratory Services (a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.	
A146	(b) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a certified contractual agreement with a certified laboratory that meets requirements of Part 493 of this chapter.	Survey Procedures: §482.27(b) Determine which services are provided directly by the facility and which are provided through contractual agreements, and determine if the referral laboratory is CLIA certified for the appropriate test specialty. Examine records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.
A147	(1) Emergency laboratory services must be available 24 hours a day.	Survey Procedures: §482.27(b)(1) Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24 hour availability of emergency services and that those services are provided when required.
A148	(2) A written description of services provided must be available to the medical staff.	Survey Procedures: §482.27(b)(2) Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat bases (either directly or under an arrangement with an outside facility). Verify that the description of services is accurate and current.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A149	(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.	Survey Procedures: §482.27(b)(3) Review tissue records (accession records, worksheets, and test reports) to determine whether the laboratory follows the written protocol. The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.
A150	(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.	Survey Procedures: §482.27(b)(4) Verify that the hospital has a written policy for examination requirements. It should list the categories of specimens that require only a gross description. Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(c) Standard: Potentially infectious blood and blood products. (1) Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.	Interpretive Guidelines: §482.27(c)(2) - (c)(8) §482.27(c)(2) - (c)(8) requires the hospital to have a system in place to take appropriate action when notified that blood or blood products it received are at increased risk of transmitting HIV. The "Awindow" period is defined as that period early in infection when the antibody to HIV is not detectable by the screening test. (Currently, the average infectious "window" period, when a person may be infected with HIV, but the HIV antibody is not detectable by current screening test methods, is approximately 22 to 25 days.) The term "repeatedly reactive" means that the initial HIV antibody screening test is reactive, retested in duplicate, and one or both of the duplicate tests are reactive. If repeatedly reactive, a licensed, more specific (confirmatory) test, e.g., Western Blot, is used to confirm the presence of HIV. "Lookback" is considered to be quarantine of products from a "window" period donor, notification of consignees (facilities having received such "window" period products) to quarantine those products, and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient. Despite the best practices of blood banks, a person may have donated blood during the "window" period. If the donor attempts to donate blood at a later date, the screening test for the antibody to HIV may, at that time, be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV and a recipient of blood or blood products collected during the "window" period would not know whether the donor was infected with HIV at the time of the previous donations. In a hospital, investigation of an incident related to lookback or the lack of lookback policy will most likely occur in response to an allegation of a hospital patient receiving HIV-infected blood or blood products. However, on a routine certification or validation survey, without a specific case to investigate, the surveyor should inquire about how the hospital plans to meet the requirements of §482.27(c) (data tags A700-A706). If a specific case is identified, determine if the hospital has developed and effectively implemented its lookback plan.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A700	(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following: (i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and (ii) The results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)	Interpretive Guidelines: §§482.27(c)(2) HCFA's regulations apply only to transfusion services in hospitals that participate in Medicare, where the transfusion service does not include more than the performance of compatibility testing, i.e., the hospital receives blood and blood products from an outside source and only performs compatibility (crossmatch) testing in preparation for transfusion to patients. Most hospitals that do not draw donors or process donor blood would fall under HCFA's regulations. FDA's regulations apply to facilities collecting, processing, and storing (manufacturing) blood and blood products, e.g., collecting donor blood, washing, or freezing red blood cells, and irradiating blood components. FDA's regulations also apply to facilities that do not participate in Medicare, such as Indian Health Services and Veteran's Administration hospitals. An independent laboratory performing compatibility testing and issuing blood and blood products directly to a non-hospital entity, i.e., home health agency, nursing facility, or ambulatory surgery center, would come under the jurisdiction of the FDA's rule as well, since it is considered a transfusion service that is not subject to the conditions of Medicare participation for hospitals. FDA's "companion" regulation to these requirements (21 CFR 610.45-610.47), also published 9/9/96, requires that, within 72 hours, blood banks notify the hospital (the consignee) for which it supplied whole blood, blood components, source plasma, or source leukocytes that are at increased risk for transmitting HIV infection and follow up this notification within 30 days of the results of the more specific (confirmatory) test for HIV. A blood bank that is part of a hospital and collects, processes, and stores (manufactures) blood products for that hospital is not required to have an agreement with the hospital administration. It would be required to meet the aforementioned FDA regulations and requirements as well as those of other regulatory and accrediting bodies. Details of agreements or practice policies are worked out between the hospital and blood bank and are consistent with applicable Federal, State, and local laws, but can be written flexibly so that any changes in FDA or HCFA requirements can be incorporated into operating procedures rather than by constructing a new agreement. Under certain circumstances, such as during blood emergencies, hospitals may receive blood from a source other than the contracted blood bank. FDA regulations require a blood bank to notify the hospital in the event it furnished the hospital with potentially HIV-infected blood.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Survey Procedures and Probes: §482.27(c)(2) o Review the written agreement for notification expectations and approval by an appropriate hospital representative. o If the hospital receives notification from the blood bank of receipt of potentially HIV-infected blood, review how and where the follow up confirmatory test results are documented. How does the hospital handle the situation where confirmatory test results are not received from the blood bank within 30 days?
A701	(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory. (i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine. (ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify all transfusion recipients in accordance with paragraph (c)(4) of this section.	Interpretive Guidelines: §482.27(c)(3) No release of quarantined blood or blood products is permitted before the results of further testing are available. If a blood bank fails to notify the hospital of the more specific (confirmatory) test results within the 30-day limit, immediate destruction of quarantined units is not required because further testing and notification was not completed within the 30 days. The blood shall not be released until the subsequent, more specific (confirmatory) test result, when reported, is negative. Interpretive Guidelines: §482.27(c)(3)(i) and (ii) The hospital's policy should reflect that release (from quarantine) of potentially HIV-infected blood is possible only if the more specific (confirmatory) test is negative, and the blood bank's (the facility that notified the hospital) records show the donor has no other informative test results that show evidence of HIV infection. "Other" informative tests are tests that a blood bank may voluntarily perform, i.e., HIV antigen tests, viral cultures, etc. If these tests are positive, the blood and blood products are disposed of if still available. The blood bank will communicate this information to the hospital. If no other informative test results exist, the hospital may release the blood and blood products from quarantine. If other informative test results exist that indicate possible HIV infection, the hospital must dispose of the blood and blood products. The reference to 21 CFR 606.40 refers to the requirements for facilities, such as hospitals, that perform blood compatibility testing. Specifically "the facility must provide for the safe and sanitary disposal of blood and blood components not suitable for use or distribution." (21 CFR 606.40(d)(2)).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Survey Procedures and Probes: §482.27(c)(3) o What is the hospital's policy for quarantining potentially HIV-infected blood and blood products? o Does it include documentation of the quarantine, follow up testing (required of the blood bank to be communicated to the hospital within 30 days), and disposal of infected blood products, if warranted? o If the hospital was notified that it had received potentially infectious blood and blood products, what did it do? o Was the potentially HIV-infectious blood quarantined according to policy? If not, why not? o Was the potentially HIV-infectious blood disposed of when confirmatory testing showed evidence of HIV infection? How was it disposed?
A702	(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions: (i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient. (ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.	Interpretive Guidelines: §482.27(c)(4) The hospital retains flexibility to develop its own policies and procedures in order to meet notification requirements. The physician of record is the first choice to notify the patient that he or she received potentially HIV-infectious blood. If the physician declines, then the notification responsibility falls to the hospital. The hospital may designate an appropriate, competent hospital representative to inform the patient. This may be another physician, such as the medical director of the transfusion service, an infection control officer, a nurse, a clinical laboratory scientist, a social worker, or a non-physician with medical expertise. This requirement also applies when the hospital transfusion service furnishes blood or blood products to another facility, such as an ambulatory surgery center, clinic, nursing facility, or home setting (via a home health agency). The hospital retains responsibility for patient notification. If the physician who orders the transfusion is not the same as the physician of record, e.g., the physician identified on the admitting form, the hospital may ask either physician to perform the notification. It is recommended that the hospital make 3 attempts within one week to notify the physician.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling (iv) Document in the patient's medical record the notification or attempts to give the required notification.	Interpretive Guidelines: §482.27(c)(4) If the hospital is unable to locate the physician, or the physician does not agree to notify the patient, the hospital should promptly make efforts to locate the patient. In this way, it is reasonable to expect the hospital to locate and notify the patient in the remaining 7 weeks. If after 3 attempts, the hospital is not able to locate the patient within the 8-week notification period, it is not expected to continue its search. However, there is no limit on how much time a hospital may choose to expend on this effort. Documentation related to notification, e.g., contacting physician, telephone log, return receipt from a certified or registered letter, becomes part of the patient's medical record. Policies and procedures for the notification process must conform to all Federal, State, and local laws regarding confidentiality. There are no Federal penalties imposed on physicians who decline to notify the patient. When the physician accepts the responsibility for notification, the hospital is not required to follow up with the physician to determine whether notification occurred. It is expected that the physician would inform the hospital if notification did not occur, but this is part of professional relationships and not a requirement. If the physician accepts responsibility for notification, and later informs the hospital that the patient was not notified, or the hospital otherwise learns that no follow up occurred, it must attempt notification, regardless of the time that elapsed after the hospital first notified the physician. Once a hospital is notified of a potentially HIV-infectious product, there is never a time that patient notification need not be attempted. It is only when, after the hospital has made a good faith effort of at least 3 attempts but is not able to locate the patient within 8 weeks, that the notification process may come to an end. Survey Procedures and Probes: §482.27(c)(4) o How does hospital policy address notification of potentially HIV-infectious blood or blood products? o Ask the hospital representative to explain what the hospital did (or would do) in the event it received such notification. o Has the hospital ever been notified that it received potentially HIV-infectious blood or blood products? If so, was follow up according to the hospital's policy? Were there any negative outcomes attributed to a breakdown in the notification process?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A703	(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless-- (i) The patient is located and notified; or (ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.	Survey Procedures and Probes: §482.27(c)(5) o How does the hospital ensure that the notification process is carried out within the 8-week timeframe specified in this requirement? o If the hospital had a lookback incident, is there documentation of notification efforts in the patient's medical record, including any extenuating circumstances that prevented patient notification within the 8-week timeframe? o If the three attempts at notification extended beyond the 8-week timeframe, what would the hospital do differently should notification be necessary in a future incident?
A704	(6) Content of notification. The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information: (i) A basic explanation of the need for HIV testing and counseling. (ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling. (iii) A list of programs or places the patient can obtain HIV testing and counseling, including any requirements or restriction the program may impose.	Interpretive Guidelines: §482.27(c)(6) This regulation does not require the hospital to provide HIV testing or counseling, but merely to refer the patient for testing and counseling. Referral for testing and counseling will be made to a physician or organization that provides high quality HIV testing and has extensive experience in providing HIV counseling. In addition, the patient should be told about any requirements or restrictions the programs may impose, such as, whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. The CDC National AIDS Hotline operates a toll-free number (1-800-342-2437) 24 hours a day that the hospital or physician can give to the patient for more assistance. A hospital that delegates notification must ensure that the notification, which includes referral for counseling, is performed in accordance with these requirements.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Survey Procedures and Probes: δ §482.27(c)(6) o What system does the hospital have in place to assist the patient in seeking testing and counseling? o What role does the patient's physician play in explaining the need for testing and counseling? o What information does the hospital make available to the patient transfused with potentially HIV-infectious blood or blood products?
A705	(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.	Interpretive Guidelines: §482.27(c)(7) Hospital requirements for confidentiality in recordkeeping exist at §482.24. Documents related to notification become part of the patient's medical record and are subject to the normal safeguards for access, information release, patient consent, and other precautions for confidential information. Hospitals must retain notification records for 5 years. Check with the State concerning special statutes regarding HIV status, testing, and confidentiality. Messages should not be left on telephone answering machines about the need for HIV testing. Any written correspondence would also need to be conducted with confidentiality in mind. Survey Procedures and Probes: §482.27(c)(7) Review the hospital's notification procedures. Was notification performed in such a manner as to ensure that names of patients requiring notification and records relating to the notification were kept confidential?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A706	(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.	Interpretive Guidelines: §482.27(c)(8) If the patient in question is competent, but the physician believes the information should not be given to the patient, and State law permits a legal representative or relative to receive information on the patient's behalf, then the physician must notify the patient's representative or relative. Upon learning of the death of the transfused patient, the hospital must pursue the notification process to inform the patient's family. It would not be appropriate for a physician or hospital to determine that the patient or someone acting on his or her behalf need not be informed. Survey Procedures and Probes: §482.27(c)(8) o Under what circumstances does the hospital determine it necessary to notify someone other than the patient who received potentially HIV infectious blood or blood products?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A181	§482.28 Condition of Participation: Food and dietetic services. The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendation on dietetic policies affecting patient treatment.	Interpretive Guidelines: §482.28 The same standards apply whether the service is provided by the hospital or contracted through an agreement. When the food and dietetic services are provided by an outside food management company, the company shall comply with all the provisions of this condition, and the contract must specify conditions of the regulatory requirements. In addition, the company shall provide a qualified dietitian (qualified through accepted professional practices) who serves on a full-time, part-time, or consultant basis and provides guidance to the administration on dietetic policies affecting patient treatment. There are sufficient personnel to respond to the dietary needs of the patient population being served. Survey Procedures: §482.28 Verify that the food and dietetic service have established policies for at least the following: o The frequency of meals served; o That acceptable hygiene practices are observed by food service staff; o The existence of a program of quality assurance for the service; o The existence of an identification system for patient trays; and o Established procedures exist to accommodate non-routine occurrences (e.g., late admissions, change in practitioner's diet orders).

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(a) Standard: Organization. (1) The hospital must have a full-time employee who-- (i) Serves as director of the food and dietetic services; (ii) Is responsible for daily management of the dietary services; and (iii) Is qualified by experience or training.		(a) Standard: Organization. (1) Verify that the director of the food and dietetic services is a full-time employee. Verify that the director has the authority and responsibility for assuring that established policies and procedures are maintained including: o Orientation, work assignments, supervision of work and food handling techniques. o Personnel performance. o Participation in regularly scheduled conferences with the administrator and department heads. o Menu planning, recommending supplies to be purchased, maintaining essential records of cost, menus, personnel, etc. Verify that the director's position description is job specific, and includes providing direction for the service. Through interviews, verify that the director implements training programs for the staff.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		Review the director's personnel folder to document training or experience. Review the director's job description to verify that the responsibility and authority for the food and dietetic services are clearly delineated.
(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.	(2) A qualified dietitian must supervise the nutritional aspects of patient care Qualification is determined on the basis of academic preparation, meeting licensure and/or registration as required by State law, and maintaining standards of professional practice.	(2) Verify that the dietitian when appropriate: o Makes an assessment of the nutritional status and adequacy of nutritional regimen. o Provides diet instructions and counseling. o Maintains pertinent patient data necessary to prescribe therapeutic and modified diets. If the qualified dietitian is not full-time, verify whether the facility makes adequate provisions for a qualified consultant. The frequency of consultation depends on the number of patients and the number of therapeutic and other diets. Verify that the dietitian takes responsibility for: o Approving of menus

(3) There must be administrative and technical personnel competent in their respective duties.

- o Patient and family counseling
- o Document nutritional status and adequacy in patient's medical records
- o Liaison with other services

(3) Visit the kitchen and observe all personnel performing assigned duties to verify adequate levels of staffing by:

- o Talking to personnel about assigned duties comparing assignments with training provided
- o Observing food handling techniques
- o Checking work schedules and assignment sheets to verify consistency in staffing for each defined function
- o Review job descriptions to verify duties are consistent with assignments in the service.

(b) Standard: Diets.

Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(b) Standard: Diets.

(1) Verify that therapeutic diet orders are prescribed by the practitioner(s) responsible for the care of that patient.

Follow the processing of a therapeutic diet from prescription through diet counseling at discharge to verify that the procedures include:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Accurate patient identification; o Transcription from nursing to dietary service; o Diet planning by a dietitian; o Regular review and updating of diet when necessary; and o Instructions to patients and their families prior to discharge. The surveyor observes preparation and serving to verify that the diets served are in conformance with the practitioner's order. Verify that diets are: o Planned in writing by a qualified dietitian. o Recorded in the patient's medical record with pertinent information about the patient's response to the therapeutic diet received as ordered. o Evaluated for nutritional adequacy.
(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.	(2) For nutritional needs, refer to the current Recommended Dietary Allowances of the Food and Nutrition Board, National Research Council. Recommended Dietary Allowances (RDAs) are revised every 5 years. The latest revision was in 1980. For broader nutritional needs, reference should be made to the principles that are outlined in the publication, Nutrition and Your Health: Dietary Guidelines for Americans, published jointly by HHS and the U.S. Department of Agriculture.	(2) Verify that: o Menus provide sufficient variety of foods served in adequate amounts at each meal to satisfy recommended dietary allowance. o A different menu is followed each day of the week. o Nourishment is provided to ensure adequate nutritional intake, when needed.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES

Check current menu and previous menus to determine whether they meet the recommended allowances that include:

- Milk - two or more cups;
- Meat group - two or more servings: beef, veal, pork, lamb, poultry, fish, eggs, occasionally dry beans or dry peas may be served as alternates;
- Vegetables and fruit group -four or more servings: a citrus fruit or other fruit and vegetable important for vitamin C; a dark green or deep yellow vegetable for vitamin A, at least every other day, other vegetables and fruits including potatoes;
- Bread and cereal group - four or more servings of whole grain enriched or restored;
- Other foods to complete meals and provide snacks.

Observe the serving of a meal to determine if the items being served are the same as those on the posted menu, and if the servings are the same quantities recommended on the daily food guide. Visit patients at mealtime to observe food acceptance.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		Talk with patients and personnel to obtain their reaction to the type of food and dietetic services provided.
(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.		(3) Determine whether the diet manual is revised as needed, usually every five years, and: o Is readily available to attending physicians, nursing and dietetic personnel; o Is appropriate for the diets routinely ordered in the facility; o Whether the standards are in accordance with those of RDA; o Diets not in compliance with RDA are so specified in the manual; and o The diet manual is the guide used for ordering and serving diets.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.30 Condition of Participation: Utilization review. The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.	§482.30 Condition of Participation: Utilization review. The plan should include: o A delineation of the responsibilities and authority for those involved in the performance of UR activities; o Review of: + The medical necessity of admissions; + The appropriateness of the setting; + The medical necessity of extended stays; and + The medical necessity of professional services.	§482.30 Condition of Participation: Utilization review. Determine that the hospital has a utilization review plan for those services furnished by the hospital and its medical staff to Medicare and Medicaid patients. Verify through review of records and reports, and interviews with the UR chairman and/or members that UR activities are being performed as described in the plan. Review the minutes of the UR committee to verify that they include: o Date of meetings; o Names of titles of members in attendance or absent; o Number of extended stay reviews approved since the last meeting with reasons for all disapprovals; and o Status report on any action taken.
(a) Standard: Applicability. The provisions of this section apply except in either of the following circumstances:	(a) Standard: Applicability. If a PRO contracr is terminated. HCFA is required to sign a new contract within 6 months. The new	(a) Standard: Applicability. Do not apply these UR requirements if:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) A Utilization and Quality Control Peer Review Organization (PRO) has assumed binding review for the hospital.	PRO will perform retrospective medical review for the interim period or HCFA can transfer interim review responsibilities to another PRO or to a Medicare intermediary or carrier.	(1) A PRO has assumed binding review for the hospital; or Medicare services or under Medicaid, the State has entered into a contract with a PRO that is deemed met under section 431.630; or
(2) HCFA has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section and has required in this section and has required the State to meet the UR plan requirements under '456.50 through '456.245 of this chapter.	Under Medicare. a PRO must perform UR functions for a hospital. Under Medicaid, the State must undertake review of UR activities in participating hospitals either directly or optionally by a PRO or other contractor. If a PRO contract exists the State Plan must comply with 42 CFR '431.630.	(2) HCFA has determined that the UR procedures established by the State under Medicaid are superior to these requirements and has required hospitals in that State to meet them. In these cases, the State requirements are applied to both Medicare and and Medicaid patients. The State requirements will then be used for survey in those States.
(b) Standard: Composition of utilization review committee.		(b) Standard: Composition of utilization review committee.
A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in '482.12(c)(1).		Determine that the governing body has delegated to the UR committee the authority and responsibility to carry out the UR function. Ascertain that at least two members of the committee are either doctors of medicine or osteopathy. The other members of the committee may be a doctor of dental surgery or medicine; a doctor of podiatric medicine; a doctor of optometry or a chiropractor in accordance with State law and hospital bylaws.
(1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following:		(1) Determine the composition of the UR committee. Verify that the committee function is the responsibility of:
(i) A staff committee of the institution;		(i) The hospital's staff or

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(ii) A group outside the institution; (A) Established by the local medical society and some or all of the hospitals in the locality; or (B) Established in a manner approved by HCFA.		(ii) A group outside the hospital: (A) Established by the local medical society and staff from some or all of the other hospitals in the locality; or (B) Established in another manner approved by HCFA. Verify that the hospital has a statement, signed by a HCFA official, as evidence of HCFA approval of its current committee.
(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(l)(ii) of this section.		(2) Verify that small hospitals, in which it is impractical to have a staff committee, delegate the function to an outside group.
(3) The committee's or group's reviews may not be conducted by any individual who-- (i) Has a direct financial interest (for example, an ownership interest) in that hospital; or		(3) Ascertain that committee members are <u>not</u>: (i) Financially involved in the the hospital (ownership of 5 percent or greater);
(ii) Was professionally involved in the care of the patient whose case is being reviewed.		(ii) Participants in the formulation or execution of the patient's treatment plan.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(c) Standard: Scope and frequency of review.		(c) Standard: Scope and frequency of review.
(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--		(1) Examine the UR plan and other documentation to determine that the medical necessity for Medicare and Medicaid patients is reviewed with respect to:
(i) Admissions to the institution;		(i) Admission;
(ii) The duration of stays; and		(ii) Duration of stay; and
(iii) Professional services furnished, including drugs and biologicals.		(iii) Professional services furnished, including drugs and biologicals.
(2) Review of admissions may be performed before, at, or after hospital admission.		(2) Admissions may be reviewed before, at, or after hospital admission as stated in the hospital's UR plan.
(3) Except as specified in paragraph (e) of this of this section, reviews may be conducted on a a sample basis.		(3) Reviews may be conducted on a sample basis, except those described below in this standard, i.e., extended stay cases.
(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and and review of professional services as follows:	(4) In a PPS hospital, to determine outlier review compliance, "reasonably assumes" is a good faith test. The question to ask is whether the hospital is reviewing outlier cases. In instances where there was no other review of outlier cases, the question is whether it was reasonable for the	(4) Determine if the hospital is reimbursed under PPS. (This does not apply to hospitals and units excluded from PPS.) Verify that the following are being reviewed:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in '412.80(a)(1)(i) of of this chapter; and	hospital not to have known that the cases were in fact outliers. Some medical judgment might be required to determine whether it is reasonable for the hospital to have assumed that a patient fell into a DRG other than the one eventually assigned by the intermediary. This would	(i) Duration of stay in cases reasonably assumed to be outlier cases; and
(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in '412.80(a)(1)(ii) of this chapter.	be an issue in long stay outlier cases where the hospital did not review because the hospital erroneously assumed that the patient was in a DRG under which the case would not have been an outlier.	(ii) Professional services in cases reasonably assumed to be outlier cases.
(d) Standard: Determination regarding admissions or continued stays.	(d) Standard: Determination regarding admissions or continued stays.	(d) Standard: Determination regarding admissions or continued stays.
(1) The determination that an admission or continued stay is not medically necessary--	(1) When other than a doctor of medicine or osteopathy makes an initial finding that the written criteria for extended stay are not met, the case must be referred to the committee, or subgroup thereof which contains at least one physician. If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified	(1) Review the UR plan and the determinations involving admissions or continued stay which are not medically necessary. Determine that these decisions are made by:
(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified in '482.12(c), concur with the		(i) One member of the UR committee, if the practitioner(s) responsible for the patient's care concurs with the determination or fails to present his/her views. The practitioner must be one of those specified in '482.12(c), or

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
determination or fail to present their views when afforded the opportunity; and	and allowed an opportunity to present his views and any additional information relating to the patient's needs for admissions or extended stay. When a physician member of the committee performs the initial review instead of a nonphysician reviewer, and he finds that admissions or extended stay is not necessary, no referral to the committee or subgroup is necessary and he may notify the attending physician directly.	
(ii) Must be made by at least two members of the UR committee in all other cases.		(ii) At least two members of the UR committee in all cases not qualified under (i) above
(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in '482.12(c) and afford the practitioner or practitioners the opportunity to present their views.	(2) If the attending physician does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final. If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient's need for extended stay, at least one additional physician member of the committee must review the case. If the two physician members determine that the patient's stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. Written notification of this decision must be sent to the attending physician,	(2) Review a sample of "medically unnecessary" decisions and verify that the practitioner or practitioners as specified in '482.12(c) were informed of the committees expected decision and were given an opportunity to comment.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	patient (or next of kin), facility administrator, and the single State agency (in the case of Medicaid) no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period. There are only 5 working days in a given week. Normally these days are Monday through Friday, however, the institution has the option to establish 5 other days as working days. When a holiday falls on a working day, that day is not counted as a working day. In no case may a nonphysician make a final determination that a patient's stay is not medically necessary or appropriate. If, after referral of a questioned case to the committee or subgroup thereof, the physician reviewer determines that an admission or extended stay is justified, the attending physician shall be so notified and an appropriate date for subsequent extended stay review will be selected and noted on the patient's record.	
(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the	(3) Written notification of this final determination must be sent to the attending physician the patient (or next of kin), the facility administrator and the single State agency (in the agency (in the case of Medicaid) no later than 2 days after such	(3) Review a sample of "medically unnecessary" cases. Verify that all involved parties are notified of the decision that care is medically not necessary no later than two days following the decision.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
hospital, the patient, and the practitioner or practitioners responsible for the care of the patient as specified in '482.12(c).	final determination and in no event later than 3 working days after the end of the assigned extended stay period. Where possible, the written notification should be received by all involved parties within the stated time period. Where appropriate and desired, verbal notification may precede written notification.	
(e) Standard: Extended stay review.		(e) Standard: Extended stay review.
(1) In hospitals that are not paid under the prospective payment system the UR committee must make a periodic review as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic review may--		(1) Review the facilities' definition of extended stay in the UR plan. Verify that the hospital's UR plan requires a periodic review of each current Medicare/ Medicaid inpatient receiving hospital services of extended duration and that the review is carried out at the specified time stated in the facility's UR plan. The review may be:
(i) Be the same for all cases; or		(i) the same for all cases; or
(ii) Differ for different classes of cases.		(ii) different for different classes of care. If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor must verify that there is a written list with lengths of stay designated for each diagnosis of functional category.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in δ412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.		(2) Determine if the hospital is under PPS. Hospitals under PPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis.
(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.		(3) Review minutes of the UR committee. Determine that the periodic reviews of extended stay are carried out on or before the expiration of the stated period or no later than 7 days after the day required in the hospital's plan.
(f) Standard: Review of professional services. The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.		(f) Standard: Review of professional services. Determine that the committee performs a review of professional services. "Professional" services mean more than physicians' services. The aspects of care rendered by laboratory personnel, physical therapists, nurses, etc., are included in this category. The review includes: o Medical necessity o Efficient use of available health facilities and services. Examples of topics a committee may review are:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Availability and use of necessary services - underuse, overuse, appropriate use; o Timeliness of scheduling of services - operating room, diagnostic; and o Therapeutic procedures, etc.
§482.41 Conditions of Participation: Physical environment.	§482.41 Conditions of Participation: Physical environment.	§82.41 Conditions of Participation: Physical environment.
The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.		
(a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.		(a) Standard: Buildings. Tour the facility to evaluate the overall hospital environment.
(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.	The hospital must comply with the applicable provisions of the Life Safety Code, NFPA 101, for emergency lighting, and with the provision of NFPA 99, Health Care Facilities, for emergency power.	(1) Use the Life Safety Code Survey Report Form, (HCFA-2786) to evaluate compliance with this item.
(2) There must be facilities for emergency gas and water supply.		(2) Check to see that arrangements have been made with utility companies or others for the provision of emergency sources of critical utilities such as water and gas or that the hospital has backup utility resources stockpiled for use in emergencies.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(b) Standard: Life safety from fire.	(b) Standard: Life safety from fire.	(b)Standard: Life safety from fire.
(1) Except as provided in paragraphs (b)(1)(i) through (b)(1)(iii) of this section, the hospital must meet the 1985 edition of the Life Safety Code of the Nation Fire Protection Association that apply to hospitals which is incorporated by reference [1].	(1) Compliance with the 1985 edition of the Code involves compliance with Chapters 1-7, 12 or 13, and Chapter 31, as well as those Standards in Appendix B which are applicable to hospitals.	(1) There is a separate survey form, (HCFA-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. (Life Safety Code Guidelines and a copy of the 1985 Life Safety Code Addendum are contained in SOM Appendix I.)
(i) Any hospital that on November 26, 1982 complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or on May 8, 1988 complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.		

[1] Incorporation of the 1985 edition of the national Fire Protection Association's Life Safety code (published February 7, 1985; ANSI/NFPA) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street, N.W., Washington, D.C. Copies may be obtained from the National Fire Protection Association, Battery March Park, Quincy, Massachusetts 02269. If any changes in this Code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(ii) After consideration of State survey agencies findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.		Waivers of Life Safety Code provisions are handled by the Fire Authority surveyor as part of the Life Safety Code survey process.
(iii) The provisions of the Life Safety Code do not apply in a State where HCFA finds that a fire and safety code imposed by State law adequately protects patients in hospitals.		
(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.		(2) Verify that there is a policy for the storage and disposal of trash. Verify through observation that these policies are adhered to.
(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.		(3) Review the hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code or State Law.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A237	(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.	Survey Procedures: §482.41(b)(4) Examine copies of inspection and approval reports from State and local fire control agencies.
A238	(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.	
A239	(1) Diagnostic and therapeutic facilities must be located for the safety of patients.	Survey Procedures: §482.41(c)(1) Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended. Check X-ray, physical therapy, and other specialized services for the appropriateness of the area for the service provided.
A240	(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.	Survey Procedures: §482.41(c)(2) Talk to the person in charge of medical equipment and determine if there is an adequate repair/periodic maintenance program. There should be a regular periodic maintenance program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer should check the equipment periodically in accordance with the manufacturer's recommendations.
A241	(3) The extent and complexity of facilities must be determined by the services offered.	Survey Procedures: §482.41(c)(3) Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A242	(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.	Survey Procedures: §482.41(c)(4) Check that all food and medication preparation areas are well lighted. An appropriate number of refrigerators and/or heating devices should be provided to ensure that food and medicine do not spoil. Verify through observation that pharmaceuticals are stored at temperatures recommended by the product manufacturer. Food products should be stored appropriately. USDA Requirements: Refrigerator, 34-40 degrees Fahrenheit - best; 34-45 degrees Fahrenheit - allowable. Freezer, zero degrees Fahrenheit - best; plus 5 degrees Fahrenheit - allowable. State or local laws may impose more stringent requirements.
		(See Pages A-110 - A-113 for Interpretive Guidelines on §482.42, Condition of Participation - Infection Control)

INTERPRETIVE GUIDLEINES - HOSPITALS		
Tag Number	REGULATION	GUIDANCE TO SURVEYORS
A350	§482.45 Condition of participation: Organ tissue and Eye Procurement	
A351	a) Standard: Organ procurement responsibilities:	Survey Procedures and Probes §482.45(a) Verify by review that the hospital has organ procurement protocols that reflect the approval of the hospital's governing body. Have any revisions and /or modifications of the written protocols been approved by the hospital's medical staff and governing body? Are there any annotated references including the date of the last review session? Ensure through staff interviews that any revisions and/or modifications have been communicated to the staff, and that staff are aware of and understand the changes
A352	1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.	Interpretive Guidelines §482.45(a)(1) When death is imminent the hospital must make the referrals both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable Survey Procedures and Probes §482.45(a)(1) Verify by review that the hospital has an agreement with a designated Organ Procurement Organization (OPO). Verify that there is a policy in place that defines "imminent death" and that it ensures timely notification of the OPO. Verify implementation of the protocols by drawing a representative sample from a list of patients who have died in the hospital in the last six months. Verify that the agreement: o Specifies criteria for referral including the referral of all individuals whose death is imminent or who have died in the hospital; o Acknowledges the OPO's responsibility to determine medical suitability for organ donation. Unless the hospital has an alternative arrangement with a different tissue and/or

<table>
<tr><th colspan="3">INTERPRETIVE GUIDLEINES - HOSPITALS</th></tr>
<tr><th>Tag Number</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>A352
(Cont.)</td><td></td><td>Eye bank, the OPO agreement acknowledges the OPO's responsibility to determine the medical suitability of tissue and/or eye donation, using the definition of the hospital designated tissue and/or eye bank for potential tissue and eye donor

o Specifies notification protocols developed by the OPOs in consultation with the hospital designated tissue and eye bank(s);

o Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreements; and

o Ensures that the designated requestor training program offered by the OPO has been developed I cooperation with and input from the tissue and eye bank designated by the hospital.</td></tr>
<tr><td></td><td></td><td>Note: Timely notification means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead.</td></tr>
<tr><td>A353</td><td>2) Incorporate an agreement with at least one tissue bank and at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and the eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;</td><td><u>Interpretive Guidelines §482.45(a)(2)</u>
If a hospital wants to inform the OPO, tissue bank, and eye bank of a death by making only one call, the OPO, functioning as gatekeeper, is required to notify the tissue bank and eye bank selected by the hospital of the death, even if the OPO has its own tissue and eye recovery service.

This agreement may be a singular one with an OPO that provides services for organ, tissue and eye, or a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

<u>Survey Procedures and Probes §482.45(a)(2)</u>
Verify by review that the hospital has an agreement with a tissue and eye bank and that the agreement:

o specifies criteria for referral of all individuals who have died in the hospital;

o Acknowledges the OPO’s responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative arrangement with a different tissue and/or eye bank;</td></tr>
<tr><td>Rev 12</td><td></td><td>A-84</td></tr>
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INTERPRETIVE GUIDLEINES - HOSPITALS		
Tag Number	REGULATION	GUIDANCE TO SURVEYORS
A353 (Cont.)		o Specifies notification protocols developed by the OPO's in consultation with the hospital designated tissue and eye bank(s); o Provides for notification of each individual death in a timely manner (as defined by the hospital in conjunction with the OPO) to the OPO (or designated third party) in accordance with the terms of the agreements; o Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with input from the tissue/or eye bank designated by the hospital. Verify compliance with the terms of the agreement when reviewing the representative sample drawn from a list of all patients who have died in the hospital in the last six months. If there is evidence that the OPO, tissue bank, or eye banks are not co-operating, how has the hospital attempted to resolve the issues? If the hospital has been unable to resolve the issue, to whom have they reported the problem
A354	3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered	<u>Survey Procedures and Probes §482.45(a)(3)</u> Verify that the hospital ensures: That individuals who approach the family are "designated requestors" or representatives of the OPO; o That the family is informed of options regarding organ/tissue donations; o That any "designated requestor" for organs has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families; and o That any "designated requestor" for tissues or eyes has been trained to request tissues or eyes What protocols are in place to ensure only designated requestors or representatives of the OPO approach families about donations? Review training schedules and personnel files to verify participation in the required training.
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INTERPRETIVE GUIDLEINES - HOSPITALS		
Tag Number	REGULATION	GUIDANCE TO SURVEYORS
A355	4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;	Interpretive Guidelines §482.45(a)(4) Using discretion does not mean a judgement can be made by the hospital, that certain families should not be approached about donation (i.e.certain religious beliefs prohibit donation). Survey Procedures and Probes §482.45(a)(5) Review the in-service training program for those staff persons designated by the hospital to notify of its options. Review the facility complaint file for any relevant complaints
A356	5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues,	Survey Procedures and Probes §482.45(a)(5) How has the hospital assured that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank? Review in-service training schedules and attendance sheets. Review the education program content to ensure the following are included: O Consent process O Importance of discretion and sensitivity O Role of the designated requestor O Transportation and donation including pediatrics O Quality improvement activities; and O Role of the organ procurement organization
A357	Reviewing death records to improve identification of potential donors, and	Survey Procedures and Probes §482.45(a)(5) Verify by review of policies and records the hospital works with OPO, tissue bank, and eye bank in reviewing death records Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.
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INTERPRETIVE GUIDLEINES - HOSPITALS		
Tag Number	REGULATION	GUIDANCE TO SURVEYORS
A357 (Cont.)		How will the effectiveness of the implemented changes be monitored and by whom? Validate that someone is identified to do the reviews and determine how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analyses Determine how confidentiality is ensured
A358	Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.	Survey Procedures and Probes §482.45(a)(5) Determine by review, what procedures are in place to ensure potential donors are identified and declared dead by an appropriate practitioner in an acceptable time frame. Verify that there are procedures in place to ensure coordination between the facility staff and OPO staff in maintaining the potential donor
A359	b) Standard: Organ transportation responsibilities 1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established an operated in accordance with § 372 of the Public Health Service (PHS) Act (41 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS ACT which are enforceable under 42 CFR 121.10 No hospital is considered to be out of compliance with § 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing	Survey Procedures and Probes §482.45(b) If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the HCFA regional office by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500
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INTERPRETIVE GUIDLEINES - HOSPITALS		
Tag Number	REGULATION	GUIDANCE TO SURVEYORS
A359 (Cont.)	2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas. #) If a hospital performs any type of transplants, it must provide organtransplant- related data, as requested by the OPTN, the Scientific Registry, and the OPO's. The hospital must also provide such data directly to the Department when requested by the Secretary.	Survey, Procedures and Probes §482.45(b)(3) Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.
Rev. 12		A-84.4

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		(See pages A-114 - A-123 for Interpretive Guidelines for §482.43, Condition of Participation--Discharge Planning.)
A250	§482.51 Condition of Participation: Surgical services. If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of the services offered.	Survey Procedures: §482.51 Tour all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o That access to the operative and recovery area is limited to authorized personnel o The conformance to aseptic technique by all individuals in the surgical area o That there is appropriate cleaning between surgical cases o That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes should be designed for maximum skin and hair coverage o That equipment is available for rapid and routine sterilization of operating room materials, and o That sterilized materials are packaged, labeled, and stored in a manner that ensures sterility, e.g., in a moisture and dust controlled environment and that each item is marked with an expiration date.
(a) Standard: Organization and staffing The organization of the surgical services must be appropriate to the scope of the services offered.		(a) Standard: Organization and staffing. Review the hospital's organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) The operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.		(1) Verify that an RN or a doctor of medicine or osteopathy is assigned responsibility for supervision of the operating rooms. Request a copy of the supervisor's position description to determine that it specifies qualifications, duties and responsibilities of the position. Verify that the supervisor is experienced and competent in the management of surgical services.
(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.		(2) Determine that an RN is available for supervision in the department or service.
(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.		(3) If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures. Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.
(4) Surgical privileges must be delineated for all practitioners surgical surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.	(4) Surgical privileges should be reviewed and updated at least every 2 years.	(4) Review the hospital's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges must also be retained in these areas.
(b) Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.	(b) Standard: Delivery of service. Policies governing surgical care should contain; at a minimum, policies for: o Aseptic surveillance and practice, including scrub techniques o Identification of infected and non-infected cases o Housekeeping requirements/ procedures o Patient care requirements - preoperative workup - patient consents and releases - clinical procedures - safety practices - patient identification procedures o Duties of scrub and circulating nurse o Safety practices o Scheduling of patients for surgery o Personnel policies unique to the O.R. o Resuscitative techniques o Care of surgical specimens o Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments o Sterilization and disinfection procedures o Acceptable operating room attire.	(b) Standard: Delivery of service. Review policies and procedures, ascertain whether they contain the minimum policies specified in the interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) There must be a complete history and physical workup in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.		(1) Review a minimum of six random medical records of surgical patients to determine that a complete history and physical examination by a doctor of medicine or osteopathy is completed prior to surgery, except in an emergency. o In all circumstances, when a history and physical is not present on the chart prior to surgery, a brief admission note on the chart is necessary. The note should include heart rate, respiratory rate, and blood pressure
(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.	(2) A complete consent form should contain at least the following information: o Name of patient, hospital and patient identification number o Name of procedure(s) or operation o Name of practitioner(s) o Signature of patient or legal guardian o Date and time consent is obtained o Signature and professional designation of person witnessing consent.	(2) Review a minimum of six random medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.
(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.		(3) Check to determine that the operating room suite has available: o Call-in-system

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Cardiac monitor o Resuscitation o Defibrillator o Aspirator (suction equipment) o Tracheotomy set
(4) There must be adequate provisions for immediate post-operative care.	(4) Adequate provisions for immediate post operative care means: o The post-operative care area or recovery room is a separate area of the hospital. Access is limited to authorized personnel. o Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following: - level of activity - respirations - blood pressure - level of consciousness - patient color o If patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.	(4) Verify that the hospital has provisions for post-operative care. o Determine that there are policies and procedures which govern the recovery room area.
(5) The operating room register must be complete and up-to-date.	(5) The register should include at least the following information: o Patient's name o Patient's hospital identification number	(5) Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	o Date of the operation o Inclusive or total time of the operation o Name of the surgeon and any assistant(s) o Name of nursing personnel (scrub and circulating) o Type of anesthesia used and name of person administering it o Operation performed.	
(6) An operative report describing, techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.	(6) The surgical report should include: o Name and hospital identification number of patient o Date of surgery o Name of surgeon and assistant(s) o Pre-operative and post-operative diagnoses o Name of the specific surgical procedure(s) performed o Type of anesthesia administered o Complications, if any o A description of techniques, findings, and the tissues removed or altered o Prosthetic devices or implants used, if any.	(6) Review a minimum of six random medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.52 Condition of Participation: Anesthesia services. If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.	§482.52 Condition of Participation: Anesthesia services. Self-explanatory	§482.52 Condition of participation: Anesthesia services. If anesthesia is administered in a hospital, then its anesthesia service must be assessed, whether or not there is an organized service. Request a copy of the organizational chart for anesthesia services. Determine that a doctor of medicine or osteopathy has the authority and responsibility for directing the administration of all anesthesia throughout the hospital. Request evidence of the director's appointment. Review the position description. Confirm that the director's responsibilities include at least the following: o Planning, directing, and supervising all activities of the service o Establishing staffing schedules, including written on-call schedule for anesthesia coverage when the department is normally closed o Monitoring of the quality and appropriateness of the anesthesia patient care o Responsibility for anesthesia services delivered in all areas of the hospital where applicable: - operating room suite(s), both inpatient and outpatient - obstetrical suite(s) - radiology department - clinics - outpatient surgery areas
(a) Standard: Organizations and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered.		(a) Standard: Organizations and staffing. Determine that the extent and complexity of the anesthesia service reflects the scope of services. Factors which affect the organization and scope of the services:

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Number of operating rooms o Number of obstetrical suites o Number of outpatient operating room procedures o Operating hours of the service o Number of anesthesiologists, CRNAs, and other persons qualified to administer anesthesia o Number, types and volume of services provided
Anesthesia must be administered by only--		Determine that a list of persons authorized to administer anesthesia is maintained in the surgical area. Review the qualifications of the individuals authorized to deliver anesthesia. Anesthesia must be administered by:
(1) A qualified anesthesiologist;	(1) A qualified anesthesiologist is a physician who has completed an approved residency training program in anesthesia. "Qualified to administer anesthesia" requires documentation of specialized training or equivalent experience in the delivery of anesthesia.	(1) An anesthesiologist as defined in the interpretive guidelines.
(2) A doctor of medicine or osteopathy (other than an anesthesiologist);		(2) A doctor of medicine or osteopathy otherwise qualified to administer anesthesia.
(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;		(3) A doctor of dental surgery or medicine or a doctor of podiatric medicine qualified under State law to administer anesthesia.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(4) A certified registered nurse anesthetist (CRNA) who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or		(4) A registered nurse certified as an anesthetist by the Council on Certification of Nurse Anesthetists (CRNA) under the supervision of the operating practitioner or an anesthesiologist who is immediately available.
(5) An anesthesiology assistant who is permitted by State law to administer anesthesia, who has successfully completed a 6-year program for anesthesiology assistants, 2 years of which consist of specialized academic and clinical training in anesthesia, and who is under the direct supervision of an anesthesiologist who is physically present.		(5) An anesthesiology assistant (PA) who has completed a 6-year program for anesthesiology, 2 years of which consists of specialized training in anesthesia. The PA must administer anesthesia under the direct supervision of an anesthesiologist. The hospital must maintain documentation of the individual's education because this level of education may not be required by State licensure or certification. Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.
(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia responsibilities. The policies must ensure that the following are provided for each patient:	(b) Standard: Delivery of services. Policies at a minimum address: o The qualifications, responsibilities and supervision required of all personnel who administer anesthesia o Patient consent o Infection control measures o Safety practices in all anesthetizing areas o Protocol for supportive life functions, e.g., cardiac and respiratory emergencies o Reporting requirements o Documentation requirements	(b) Standard: Delivery of services. Review the policies developed on anesthesia procedures. Determine that the anesthesia service incorporates the minimum policies identified in interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) A preanesthesia evaluation performed within 48 hours prior to surgery by an individual qualified to administer anesthesia under paragraph (a) of this section.	(1) The preoperative anesthetic evaluation should include: o Notation of anesthesia risk o Anesthesia, drug and allergy history o Any potential anesthesia problems identified o Patient's condition prior to induction of anesthesia.	(1) Review records to determine that each patient has a preanesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed within 48 hours prior to surgery.
(2) An intraoperative anesthesia record.	(2) The intraoperative anesthesia record should include: o Name, dosage, route and time of administration of drugs and anesthesia agents o I.V. fluids o Blood or blood products, if applicable o Oxygen flow rate o Continuous recordings of patient status noting blood pressure, heart and respiration rate. o Any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.	(2) Review records to determine that each patient has an intraoperative anesthesia record documenting all pertinent events taking place during anesthesia.
(3) With respect to inpatients, a postanesthesia followup report written within 48 hours after surgery by the individual who administers the anesthesia.	(3) The postanesthesia followup report should document the following: o Cardiopulmonary status o Level of consciousness o Any follow up care and/or observations o Any complications occurring during postanesthesia recovery.	(3) Review records to determine that a postanesthesia followup report is written for each patient by the individual who administered the anesthesia within 48 hours after surgery. Documentation should include those items specified in interpretive guidelines.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.		(4) Review records to determine that outpatients have a postanesthesia evaluation for proper anesthesia recovery in accordance with hospital policies and procedures. Depending on the type of anesthesia and length of surgery, the postoperative check should include the items listed in the interpretive guidelines.
§482.53 Condition of Participation: Nuclear medicine services.	§482.53 Condition of Participation: Nuclear medicine services.	§482.53 Condition of Participation: Nuclear medicine services.
If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.	If nuclear medicine services are provided under arrangement, the governing body must ensure that the services are provided in a safe and effective manner, in accordance with 482.12(e).	Verify that the facility has complied with the appropriate Federal requirements by reviewing the hospitals' permit or license from the State or, if necessary contact the State Radiation Health Division or other State or Federal agency that has the responsibility, for confirmation. If necessary, request assistance from the State Radiation Health Division.
(a) Standard: Organization and staffing.		(a) Standard: Organization and staffing.
The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.		Verify through review of policies, procedures, other documentation and interview of nuclear medicine personnel that the organization of the service reflects the extent and complexity of services provided, as specified by the medical staff.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine. (2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.		(1) Verify that: o The qualifications, training, functions and responsibilities of the of the nuclear medicine service personnel are specified by the service director, have been approved by the medical staff, and o Personnel are performing duties that have been specified for them.
(b) Standard : Delivery of Service. Radioactive materials must be prepared, labeled, used, transported, stored and disposed of in accordance with acceptable standards of practice.		(b) Standard: Delivery of Service. Review policies and other records to determine that standards are established regarding the: o Handling of equipment o Protection of patients and and personnel from radiation hazards o Testing of equipment for radiation hazards o Maintenance of personnel radiation monitoring devices

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Storage and disposal of radionuclides and radiopharmaceuticals. Determine through observation of the functioning of the nuclear medicine service that safety precautions are practical and enforced and that personnel and patients, where indicated, wear appropriate body shielding (such as lead aprons and lead gloves).
(1) In-house preparation of radio-pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine		(1) Verify that the preparation of radiopharmaceuticals is performed or directly supervised by an appropriately trained pharmacist or doctor of medicine or osteopathy. or osteopathy.
(2) There is proper storage and disposal of radioactive materials.		(2) Verify through inspection and records that radioactive materials are properly stored and disposed of.
(3) If clinical laboratory tests are performed in the nuclear medicine service, the service must meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control (See 482.27(a), (b), (e), and (f).		(3) See survey procedures for section 482.27 a, b, e, and f in appendix C of this manual, if appropriate. Determine that all radioactive materials, reagents and standards are prepared, stored and checked at a defined interval determined by the director to assure accuracy, patient safety and precision of results. Examine the reagents and standards for proper storage and signs of deterioration, and that they are not being used beyond the

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(c) Standard: Facilities. Equipment and supplies must be appropriate for for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be-- (i) Maintained in safe operating condition; and (ii) Inspected, tested, and calibrated at least annually by qualified personnel.	(c) Standard: Facilities. The nuclear medicine service is provided in accordance with applicable Federal and State regulations and recommendations governing radiation safety. (See 21 CFR Subpart J, Radiological Health, and 10 CFR Chapter 1, Part 20, U.S. Nuclear Regulatory Commission standards for protection against ionizing radiation. - All in vitro tests and all invivo procedures classified under radiobioassay must be performed in accordance with the requirements in 482.27 a, b, e, and f including quality control calibration and record retention, etc.	(c) Standard: Facilities Reagents are labeled to assure proper identification, use, storage and safe handling and date of preparation and assay. (i) Verify that the nuclear medicine service has a preventive maintenance schedule which is followed to assure proper and safe equipment performance. (ii) Verify that records of calibration and accuracy of test equipment are reviewed to assure patient safety and adequate test performance. All safety survey equipment is calibrated at least annually. Verify that equipment for radionuclide measurements are assured to be in proper operating condition to assure accurate results and patient safety each day of use.
(d) Standard: Records. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures. (1) The hospital must maintain copies of nuclear medicine reports for at least five years.		(d) Standard: Records. Verify that the hospital has policies for maintaining signed and dated nuclear medicine reports. (1) Verify that copies of nuclear medicine reports are maintained for five years.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretations of these tests.		(2) Verify that reports of nuclear medicine interpretations are signed and dated by practitioners authorized by the medical staff to perform these interpretations.
(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.		(3) Verify that there are accurate records maintained regarding the receipt and disposition of radiopharmaceuticals.
(4) Nuclear medicine services must be ordered only by a practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.		(4) Verify that nuclear medicine services are ordered only by practitioners authorized to do so by the medical staff, consistent with Federal and State licensure.
§482.54 Condition of Participation: Outpatient services.	§482.54 Condition of Participation: Outpatient services.	§482.54 Condition of Participation: Outpatient services.
If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.	Self-explanatory.	Facilities must be adequate to provide examinations, diagnostic tests and treatment regimens that meet acceptable standards of practice.
(a) Standard: Organization.		(a) Standard: Organization.
Outpatient services must be appropriately organized and integrated with inpatient services.		o Verify that the outpatient services are organized to provide the type and volume of care needed by the patients presenting themselves for care. o Verify that there are established methods of communication as well as established procedures to assure integration with inpatient services that provide continuity of care.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
		o Review of random sample of medical records of outpatients who were admitted to determine that pertinent information from the outpatient record is in the inpatient record. o Verify that there are no uncorrected documented instances of failure to meet acceptable standards of practice.
(b) Standard: Personnel. The hospital must-- (1) Assign an individual to be responsible for outpatient services, and (2) Have appropriate professional and non-professional personnel available.		(b) Standard: Personnel. (1) Verify that one person is assigned to manage and be responsible for outpatient services. (2) Compare duty rosters to patient log to verify that sufficient physicians, nurses and other staff are available to provide medical care.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
§482.55 Condition of Participation. Emergency services.	§482.55 Condition of Participation. Emergency services.	§482.55 Condition of Participation. Emergency services.
The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.	Self-explanatory	
(a) Standard: Organization and direction.		(a) Standard: Organization and direction.
If emergency services are provided at the hospital:		
(1) The services must be organized under the direction of a qualified member of the medical staff; and		(1) Verify that emergency services are organized under the direction of a qualified member of the medical staff.
(2) The services must be integrated withother departments of the hospital.		(2) Verify that there are established procedures to assure integration with either hospital services including laboratory, radiology and operating services to provide continuity of care.
(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.		(3) Verify that procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis.
(b) Standard: Personnel		(b) Standard: Personnel
(1) The emergency services must be supervised by a qualified member of the medical staff.		(1) Verify that a qualified member of the medical staff is designated to supervise emergency services.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.	(2) There are sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.	(2) Verify that there are sufficient medical and nursing personnel qualified in and needs anticipated by the facility and that there are specific assigned duties for emergency care personnel and a clear chain of command. O Interview staff to determine that they re knowledgeable, within their own level of participation in emergency care including: Parental administration of electrolytes, fluids blood and blood components; Care and management of injuries to extremities and central nervous system; and Prevention of contamination and cross infection.
§482.56 Conditions of Participation: Rehabilitation services.	§482.56 Conditions of Participation: Rehabilitation services.	§482.56 Conditions of Participation: Rehabilitation services.
If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.		
(a) Standard: Organization and staffing.	(a) Standard: Organization and staffing.	(a) Standard: Organization and staffing.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
The organization of the service must be appropriate to the scope of the services offered.	Each service, whether provided through a single discipline department or within a multi-discipline department, functions with established lines of authority and responsibility that ensure accountability in patient care and administrative matters regarding the provision of the service.	Review administrative and patient care policies, organizational charts, position descriptions and, if the services are provided under an agreement, review policies and contracts to determine responsibilities and delegations of authority relative to each service provided. For each service an adequate number of qualified staff is available to ensure safe and efficient provision of services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of treatment required. At least one qualified professional must be on the premises to: o Evaluate each patient; o Initiate the plan of treatment; and o Instruct and supervise supportive personnel when they are used to furnish services. Review medical records to document that a qualified professional evaluates the patient and initiates the treatment.
(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.	(1) Each service must be accountable to an individual that directs the overall operation of the service. An individual may serve as director of more than one service either as the director of a multiservice department or as the director of single service departments.	(1) Review the organization and policies and procedures under which services are provided to determine the director's responsibility.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	The director may be part-time or full-time. In all situations the director retains professional and administrative responsibility for personnel providing the service. If the director is part-time, the time spent directing the service should be commensurate with the scope of services provided.	Verify through a review of the director's position description that the director has the authority and responsibility for seeing that services are provided consistent with facility policies, State law, and accepted standards of practice. Discussion with the director will assist in determining if he/she has the necessary knowledge, experience and capabilities.
(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, mustbe provided by staff who meet the qualifications specified by the medical staff, consistent with State law.		(2) Review medical staff documentation to ascertain that they have established staff qualifications as appropriate, for physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and audiologists consistent with State law. Documentation should be available indicating the service provided and the various level of personnel permitted to provide the service. Verify that there is a procedure for periodically reviewing the qualifications and keeping informed of changes in State law pegarding personnel qualification.
(b) Standard: Delivery of services. Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patients's daily records.	(b) Standard: Delivery of services. Verbal orders regarding treatment are acceptable if documented and signed by the person accepting the order. The time, date, and contents of the verbal order and the practitioners name must be	(b) Standard: Delivery of services. Verify that each patient has a plan of treatment established in writing prior to the beginning of treatment. The plan is established by the practitioner ordering the service in collaboration with an individual qualified to provide the service.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
	entered in the record at the time of the order and be countersigned by the practitioner as soon as possible.	Initially the plan may be general in nature but is developed in more detail subsequent to evaluation of the patient by qualified personnel. The plan should include treatment goals and type, amount, frequency and duration of services. Changes in the treatment plan should be documented in writing and supported by clinical record information such as evaluations, test results, or orders.
§482.57 Condition of Participation: Respiratory care services.	§482.57 Condition of Participation: Respiratory care services.	§482.57 Condition of Participation: Respiratory care services.
The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.	Self-explanatory.	Determine if the hospital provides respiratory care services. If any degree of respiratory care is administered in the hospital, evaluate for compliance with this requirement. Verify that the type and amount of care meet the needs of the patients.
(a) Standard: Organization and staffing.		(a) Standard: Organization and staffing.
The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.		Review the hospital's organizational plan displaying the relationship of the respiratory care service to other services as appropriate to the scope and complexity of the services offered. Verify that the scope of the diagnostic and therapeutic respiratory care services offered is defined in writing.
(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the services properly. The director may serve on either a full-time or part-time basis.		(1) Verify that a director has been appointed and that he/she has fixed lines of authority and delegated responsibility for operation of the service. Ascertain that the director is an M.D. or D.O. The director may serve either full-time or part-time.

REGULATIONS	INTERPRETIVE GUIDELINES	SURVEY PROCEDURES
(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistant with State law.	(2) There are sufficient personnel to respond to the respiratory care needs of the patient population being served.	(2) Determine that there are written staffing schedules which correlate the numbers and types of personnel to the numbers and type of treatments furnished. Review the qualifications spevified by the medical staff and requiredby State law to determine that the personnel are qualified.
(b) Standard: Delivery of service. Services must be delivered in accordance with medical staff directives.		(b) Standard: Delivery of service. Determine that these services are delivered in accordance with medical staff directives. Review the written directives or policies. As appropriate to the service provided, that they address: o Equiptment assembly and operation o Steps to be taken in the advent of adverse reactions o Handling, storage, and dispensing of therapeutic gases o Safety practives o Infection control meaasures o Cardiopulmonary resusitation o Obtaining blood samples and their analysis o Pulmonary function testing o Therapeutic percussion and vibration

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A312		Survey Procedures: §482.57(b) o Bronchopulmonary drainage o Mechanical ventilatory and oxygenation support o Aerosol, humidification, and therapeutic gas administration o Administration of medications
A313	(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.	Survey Procedures: §482.57(b)(1) Verify that specific procedures are performed and supervised in accordance with hospital written policies which must include: o Each type of respiratory care service provided in the hospital; o Type, education, training, and experience of personnel authorized to perform each type of respiratory care, whether they may perform it without direct supervision; and o The type of personnel who is qualified to provide the direct supervision.
A314	(2) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency testing, and quality control. (See §482.27(a), (b), (e), and (f) for requirements applicable to laboratories).	Survey Procedures: §482.57(b)(2) Refer to the guidelines under §482.27(a), (b), (e), and (f) for independent laboratory if blood gases and laboratory tests are performed in the respiratory care unit.
A315	(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.	Survey Procedures: §482.57(b)(3) Examine the charts of patients for whom respiratory care has been ordered to assure that services are provided only on the orders of doctors of medicine or osteopathy, and that services are provided in accordance with those orders.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A243	§482.42 Condition of Participation: Infection Control. The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.	Interpretive Guidelines: §482.42 Because of the risk of nosocomial infections and communicable diseases, there must be an active surveillance program of specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the hospital. There must be a mechanism to evaluate the program(s) and take corrective action. The program must include implementation of a nationally recognized system of infection control guidelines to avoid sources and transmission of infections and communicable diseases. One nationally recognized reference on infection control is the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections. Another is the Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities. An active infection control program should have policies which address the following: o Definition of nosocomial infections and communicable diseases; o Measures for assessing and identifying patients and health care workers (HCWs) at risk for infections and communicable diseases; o Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases; o Methods for obtaining reports of infections and communicable diseases on inpatients and HCWs in a timely manner; o Measures for prevention of infections, especially those associated with intravascular therapy, indwelling urinary catheters, tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection; o Measures for prevention of communicable disease outbreaks, especially tuberculosis; o Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease; o Isolation procedures and requirements for infected or immunosuppressed patients;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		o Use and techniques for standard precautions; o Education of patients and their significant others about infections and communicable diseases; o Methods for monitoring and evaluating practices of asepsis; o Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean from dirty, as well as other means for limiting the spread of contagion; o Authority and indications for obtaining microbiological cultures from patients; o A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children; o Orientation of all new hospital personnel to infections, communicable diseases, and to the infection control program; o Measures for the screening and evaluation of HCWs for communicable diseases, and for the evaluation of HCWs exposed to patients with non-treated communicable diseases; o Employee health policies regarding infectious diseases and when infected or ill employees must not render direct patient care; o A procedure for meeting the reporting requirements of the local health authority; and o Provision for program evaluation and revision of the program, when indicated. Survey Procedures and Probes §482.42 Tour the hospital, observe the environment, and interview the infection control officer(s). Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Determine that this system is an active program, that it is both hospital-wide and program-specific, and that it is being enforced. Note that the cleanliness of horizontal surfaces, bedside equipment, and air inlets because infectious organisms may spread from these places.
A244	(a) Standard: Organization and Policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.	Interpretive Guidelines: §482.42(a) An infection control committee may delegate responsibility for infection functions, if the hospital desires. Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.
A245	(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.	Interpretive Guidelines: §482.42(a)(1) The infection control officer(s) is responsible for: o Implementing policies governing asepsis and infection control; o Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and hospital personnel; o Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and hospital personnel, especially those occurring in clusters; o Preventing and controlling the spread of infections and communicable diseases among patients and patient care staff; o Cooperating with hospital-wide orientation and inservice education programs; o Cooperating with other departments and services in the performance of quality assurance activities; and o Cooperating with disease control activities of the local health authority.

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		Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.
A246	(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.	Interpretive Guidelines: §482.42(a)(2) Verify that the reporting of infections and communicable diseases and the maintenance or appropriate records includes a log of incidents related to infections and communicable diseases.
A247	(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing must -- (1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas.	Interpretive Guidelines: §482.42(B) Determine that the infection control program is coordinated by the chief executive officer, the medical staff, and the Director of Nursing Services with the hospital's quality assurance in-service training programs. Determine that problems identified are reported to the medical staff, nursing and administration, and addressed in the hospital's quality assurance and in-service training programs. Determine that the chief executive officer, the medical staff, and the Director of Nursing Services are responsible for implementing corrective action plans in problem areas, that the plans are evaluated for effectiveness and revised if needed, and that documentation concerning corrective actions and outcomes are maintained.

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A330	§482.43 Condition of Participation: Discharge Planning The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.	Interpretive Guidelines: §482.43 The written discharge planning process must reveal a thorough, clear, comprehensive process which is understood by the hospital staff. Survey Procedures and Probes: §482.43 Review hospital written policies and procedures to determine the existence of a discharge planning process. Interview a sample of hospital staff who are involved in direct patient care. Ask the following questions: o How is discharge planning conducted at this hospital? o How are you kept apprised of the hospital's policies and procedures for discharge planning?
A331	(a) Standard: Identification of patients in need of discharge planning. The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.	Interpretive Guidelines: §482.43(a) Medicare participating hospitals are afforded great flexibility in setting the criteria for identifying patients who are likely to suffer adverse health consequences upon discharge without adequate discharge planning. Presently there is no nationally accepted tool or criteria for identifying these individuals. However, the following factors have been identified as important: functional status, cognitive abilities, and family support. Patients at high-risk of requiring post-hospital services must be identified through a screening process. The hospital should reevaluate the needs of the patients on an ongoing basis, and prior to discharge, as they may change based on the individual's status. There is no set time frame for identification of patients requiring a discharge planning evaluation other than it must be done as early as possible. The timing is left up to the hospital, its staff, and attending physician. Survey Procedures and Probes: §482.43(a) Review the hospital's high-risk screening procedure. o How does the hospital's high-risk screening procedure work?

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		o What staff are involved? Who is ultimately accountable? o How is the procedure evaluated to make sure patients are appropriately evaluated (do not suffer adverse consequences due to inappropriate evaluation)?
A332	(b) Standard: Discharge planning evaluation. (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.	Interpretive Guidelines: §482.43(b)(1) The needs assessment can be formal or informal. A needs assessment generally includes an assessment of factors that impact on an individual's needs for care after discharge from the acute care setting. These may include assessment of biopsychosocial needs, the patient's and caregiver's understanding of discharge needs, and identification of post-hospital care resources. At the present time, there is no nationally accepted standard. The purpose of a discharge planning evaluation is to determine continuing care needs after the patient leaves the hospital setting. It is not intended to be a care planning document. The hospital may develop an evaluation tool or protocol. Survey Procedures and Probes: §482.43(b)(1) Interview a sample of hospital staff and ask: o How are patients made aware of their rights to request a discharge plan? Talk to a sample of patients and family members who are expecting a discharge soon and ask: o Did the hospital staff assist them in planning for post-hospital care? Does the patient/family express that they feel prepared for discharge? o Are you given the pamphlet, "Important Message from Medicare"? o Are you aware that you may request assistance with discharge planning?

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A333	(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.	Interpretive Guidelines: §482.43(b)(2) Responsibility for discharge planning is often multidisciplinary; there is no restriction to a particular discipline. The hospital has flexibility in designating the responsibilities of the registered nurse, social worker, or other appropriate qualified personnel for discharge planning. The responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge clinical and social needs and assessment skills. Ideally, discharge planning will be an interdisciplinary process, involving disciplines with specific expertise, as dictated by the needs of the patient. For example, for a patient with emphysema, the discharge planner could coordinate respiratory therapy and nursing care and financial coverage for home care services, oxygen equipment, and patient/caregiver education utilizing cost effective, available community services in an expedient manner. Survey Procedures and Probes: §482.43(b)(2) o Review the written policy and procedure that designates discharge planning responsibilities. o Review the job descriptions of the designated personnel for discharge planning expectations. o Ask the designated personnel to describe their qualifications for and experience with discharge planning and evaluate whether they are congruent with the community standard of practice. o If licensing is required, current credentials must be on file.
A334	(a) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.	Interpretive Guidelines: §482.43(b)(3) The hospital is responsible for developing the discharge plan for patients who need a plan and for arranging its initial implementation. The hospital's ability to meet discharge planning requirements is based on the following: (1) implementation of a needs assessment process with high risk criteria identified; (2) complete, timely, and accurate assessment; (3) maintenance of a complete and accurate file on community-based services and facilities including long term care, subacute care, home care or other appropriate levels of care to which patients can be referred; and (4) coordination of the plan among various disciplines responsible for patient care.

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		The hospital has latitude to demonstrate this function in the most efficient way possible. Survey Procedures and Probes: §482.43(b)(3) o What is the process the hospital uses to identify patients who need a discharge plan? o Does the hospital use quality assurance and/or utilization review screens that determine whether the discharge planning process effectively identifies patients in need of plans, and whether the plans are adequate and appropriately executed? o Review clinical records of several patients identified for discharge planning for appropriateness, adequacy, and execution; ask staff responsible for the patients' care to describe the steps taken to implement the plan initially for the selected patients. o Ascertain whether various disciplines are involved with discharge planning, including physical, speech, occupational, and respiratory therapists and dietitians, in addition to physicians, nurses, and social workers.
A335	(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.	Interpretive Guidelines: §482.43(b)(4) The capacity for self-care includes the ability and willingness for such care. The choice of a continuing care provider depends on the self-care components, as well as, availability, willingness, and ability of family/caregivers and the availability of resources. The hospital must inform the patient or family as to their freedom to choose among providers of post-hospital care, where possible. Patient preferences should also be considered; however, preferences are not necessarily congruent with the capacity for self- care. Patients should be evaluated for return to the pre-hospital environment, but also should be offered a range of realistic options for consider for post-hospital care. This includes patients admitted to a hospital from a SNF, who should be evaluated to determine an appropriate discharge site. Hospital staff should incorporate information provided by the patient and/or caregivers to implement the process.

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		Survey Procedures and Probes: §482.43(b)(4) o Gather information about the patient's self-care capacity from the clinical record, direct clinical observation, and information obtained from the patient, caregiver, and staff involved in the care of the patient; judge appropriateness of discharge disposition. o Note if appropriate interdisciplinary input is documented. o Did the patient and/or caregiver participate in the needs assessment and decision for post-hospital care resources? o Is a patient who was admitted from a SNF given a full-range of realistic options for post-hospital continuation of care?
A336	(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.	Interpretive Guidelines: §482.43(b)(5) Patient hospital length of stay varies widely. The timing of the discharge evaluation should be relative to the patient's clinical condition and anticipated length of stay. Assessment should start as soon after admission as possible and be updated periodically during the episode of care. Information about the patient's age and sex could be collected on admission while functional ability data is best collected closer to discharge, indicating more accurately a patient's continuing care requirements. Survey Procedures and Probes: §482.43(b)(5) o Review several patients' discharge plans for the appropriate coordination of health and social care resources based on the individual patient's and caregiver's post-hospital needs. o Is there a pattern of prolonged length of stay for certain patient populations because implementation of post-hospital care was delayed? If so, is the delay due to circumstances beyond the hospital's control (e.g., inability to reach the beneficiary's responsible person(s)), and/or is the delay due to poor hospital planning for timely post-hospital arrangements?

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A337	(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.	Interpretive Guidelines: §482.43(b)(6) The hospital must demonstrate its development of discharge plans for patients in need and the initial implementation of the plan. Documentation of these activities is expected, but the hospital has the latitude to demonstrate this in the most efficient way possible. The discharge plan generally can be found in the clinical notes if there is no dedicated form. The hospital will be expected to document its decision about the need for a plan, document the existence of plans when needed, and indicate what steps were taken to implement the plans initially. Evidence of an ongoing evaluation of the discharge planning needs is the important factor. Documented evidence of discussion of the evaluation with the patient (if possible), interested persons, and the next caregiver should exist in the medical record. Although not mandated, it is preferable that the hospital staff seek information from the patient and family to make the discharge plan as realistic and viable as possible. Survey Procedures and Probes: §482.43(b)(6) o Review several clinical records for evidence of a discharge planning evaluation. o Through review of the clinical record notes and questioning of the patient and/or caregiver and staff, verify discussion of the evaluation with the involved persons.
A338	(c) Standard: Discharge Plan (1) A registered nurse, social worker, or other appropriately qualified personnel must develop or supervise the development of a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.	Interpretive Guidelines: §482.43(c)(1) It is a management function of the hospital to ensure proper supervision of its employees. Existing training and licensing requirements of a registered nurse and social worker in discharge planning are sufficient; "other appropriately qualified personnel" may include a physician. The hospital should determine who has the requisite knowledge and skills to do the job regardless of how these were acquired. However, because post-hospital services and, ultimately, the patient's recovery and quality of life can be affected by the discharge plan, the plan should be supervised by qualified personnel to ensure professional accountability. Survey Procedures and Probes: §482.43(c)(1) o Examine patients' clinical records for references to a registered nurse, social worker, or other designated qualified personnel or their signature on a written discharge plan notation.

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		o Ask staff to describe who oversees the development of a discharge plan.
A339	(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.	Interpretive Guidelines: §482.43(c)(2) The physician can make the final decision as to whether a discharge plan is necessary. The hospital will develop a plan if a physician requests one even if the interdisciplinary team had determined one to be unnecessary. Survey Procedures and Probes: §482.43(c)(2) o Review the hospital policy and procedure to determine who may request a discharge plan. o Is there reference to or existence of a discharge plan in the clinical record when requested by a physician. o Ask a physician involved with discharge planning about experiences with requesting development of discharge plans when the interdisciplinary team does not recommend a plan.
A340	(3) The hospital must arrange for the initial implementation of the patient's discharge plan.	Interpretive Guidelines: §482.43(c)(3) The hospital is required to arrange for the initial implementation of the discharge plan. This includes arranging for necessary post-hospital services and care, and educating patient/family/caregivers /community providers about post-hospital care plans. Survey Procedures and Probes: §482.43(c)(3) o There is documented evidence of implementation of the discharge plan, including contact and transmission of information to the patient (when possible) and the next caregiver.

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A341	(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.	Interpretive Guidelines: §482.43(c)(4) The discharge planning evaluation should be initiated as soon as possible after admission and updated as changes in the patient's condition and needs occur, and, as close as possible to the patient's actual discharge. Survey Procedures and Probes: §482.43(c)(4) o Review the hospital's policy on reassessment of discharge plans. o Review several clinical records for evidence of reassessment of the patient and related changes with regard to the care plan/critical pathway(s) in the discharge plan when warranted. o Ask staff involved with discharge planning to discuss the reassessment process and/or present a clinical record that documents reassessment.
A342	(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.	Interpretive Guidelines: §482.43.(c)(5) Evidence should exist that the patient and/or family and/or caregiver is/are provided information and instructions in preparation for post-hospital care and kept informed of the progress. Hospital personnel are in the best position to judge the appropriate time for such guidance. Use of family caregivers in providing post-hospital care should occur when the family is both willing and able to do so. It is appropriate to use community resources with or without family support whenever necessary. Survey Procedures and Probes: §482.43(c)(5) o Where possible, interview patients and their family members to determine whether they have been instructed in post-hospital care, e.g., medication administration, dressing changes, and cast care. If the patient is being transferred to an alternate care delivery setting, has this information been shared with the patient? o Is there documentation that care instruction has been communicated to the post-hospital care setting?

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A343	(d) Standard: Transfer or referral. The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.	Interpretive Guidelines: §482.43(d) The hospital must ensure that patients receive proper post-hospital care within the constraints of a hospital's authority under State law and within the limits of a patient's right to refuse discharge planning services. If a patient exercises the right to refuse discharge planning or to comply with a discharge plan, documentation of the refusal is recommended. "Medical information" may be released only to authorized individuals according to provision §482.24(b)(3). Examples of necessary information include functional capacity of the patient, requirements for health care services/procedures, discharge summary, and referral forms. "Appropriate facilities" refers to facilities that can meet the patient's assessed needs on a post-discharge basis and that comply with Federal and State health and safety standards. Survey Procedures and Probes: §482.43(d) o Ask staff involved with discharge planning to describe the process of transfer of patient information from the hospital to a post-discharge facility. o Does the process assure continuity of care? o Are the patient's rights, such as for confidentiality, refusal, and preference considered? o If required, is there evidence of written authorization by the patient before release of information?
A344	(e) Standard: Reassessment. The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.	Interpretive Guidelines: §482.43(e) The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process. Although specific parameters or measures that would be included in a reassessment are not required, the hospital should assure the following factors in the reassessment process: 1. Time effectiveness of the criteria to identify patients needing discharge plans; 2. The quality and timeliness for discharge planning evaluations and discharge plans;

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		3. The hospital discharge personnel maintain complete and accurate information to advise patients and their representatives of appropriate options; and 4. The hospital has a coordinated discharge planning process that integrates discharge planning with other functional departments, including the quality assurance and utilization review activities of the institution and involves various disciplines. Survey Procedures and Probes: §482.43(e) o Review hospital policies and procedures to determine how often the discharge planning process is reassessed. o Ask hospital staff how often the discharge planning process is reassessed. What data is examined to determine how well the process is working in providing for continued care of the patient?

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A500	§482.66 Condition of Participation: Special requirements for hospital providers of long-term services ("swing-beds"). A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in §409.30, and be reimbursed as a swing-bed hospital, as specified in §405.434:	Interpretive Guidelines: §482.66 Note: Small rural hospitals frequently have an excess of hospital beds and the communities in which they are located often have a scarcity of SNF or ICF beds in Medicare and Medicaid participating facilities. The swing-bed concept allows hospitals to use their beds interchangeably as either hospital, SNF, or ICF beds to have greater flexibility in meeting fluctuating demands for acute and long-term care.
A501	(a) Standard: Eligibility A hospital must meet the following eligibility requirements: (1) The facility has fewer than 50 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see §405.453(d)(5));	Survey Procedures: §482.66 (a) (1) & (2) Compliance with eligibility standards is assessed prior to the survey. The swing-bed Condition of Participation was set up so that the Medicare SNF-type services in a swing-bed hospital are subject to the same requirements as services furnished in a SNF except for those standards that: (1) duplicate existing hospital requirements; (2) require a facility to make extensive structural modifications or changes; or (3) are unnecessary in what is primarily a general routine hospital setting. This information is presented so that the surveyor will apply the SNF-type services requirements in appropriate context--flexibility for hospitals to meet the needs of the community balanced by equity in the
A502	(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census;	

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(3) When required by the State in which it is located, the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under §1521 of the Public Health Service Act);		Assurance of health and safety. Therefore, when making compliance decisions, focus on consistent application of the requirements to which both skilled nursing facilities and swing-bed hospitals must adhere.
(4) The hospital does not have in effect a 24-hour nursing Waiver granted under §405.1910(c); and		
(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.		
(b) Facility services. Standard: Skilled nursing : The facility is substantially in compliance with the following skilled nursing facility requirements contained in Subpart K of Part 405 of this chapter		(b) Standard: Skilled nursing facility services. Verify compliance with the applicable SNF standards as specified.
(1) Patient rights (§405.1121(k)). The governing body of the facility establishes written policies regarding the rights and responsibilities of patients and, through the administrator, is responsible for development of and adherence to procedures implementing such policies. These policies and procedures are made available to patients, to any guardians, next of kin, sponsoring agency(ies) or representative payees selected pursuant to section 205(j) of the Social Security Act, and Subpart Q of 20 CFR Part 404,		(1) Patient's Rights (§405.1121 (k)). Determine that the hospital has written policies regarding patients' rights. Base the determination on the following: (2) Verify that the facility makes available to patients, and explains as necessary, a list of the kinds of services and articles provided by the facility. The list identifies nursing care, services and items (laundry, cosmetics, beautician services,

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and to the public. The staff of the facility is trained and involved in the implementation of these policies and procedures		etc.) Charges for all services and supplies not included in the facility's basic per diem rate are identified. Items covered under Medicare and/or Medicaid are clearly indicated, as well as all items that will be charged directly to the patient. These should be reviewed with the patient by a designated staff member.
These patients' rights policies and procedures ensure that, at least, each patient is admitted to the facility:		
(i) 405.1121(k)(2). Is fully informed, prior to or at the time of admission and during stay, of services available in the facility, and of related charges including any charges for services not covered under Title XVIII and XIX of the Social Security Act or by the facility's basic per diem rate;		(i) Interview patients to determine if they understand what services and supplies are available and their fiscal responsibilities, if any. NOTE: A list of services provided under the Medicaid program is available to the surveyors from the State agency. Verify that patients are informed in advance of any changes in the costs or availability of services.
(ii) 405.1121(k)(3). Is fully informed, by a physician, of his medical condition unless medically contraindicated (as documented, by a physician, in his medical record), and is afforded the		(ii) Verify through interview f a number of patients hat their plan of care has been discussed with them and whether they have had the opportunity to participate in planning. Determine whether patients are advised of alternative

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opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research;		courses of treatment and their consequences when such alternatives are available. Review a sample of medical records of patients who have not been informed of their conditions to verify the physician's statement of medical contraindication. Determine whether any patients are participating in experimental research and interview them about their knowledge and awareness of the experiment or verify that patients' written informed consentwas received prior to participation.
(iii) 405.1211(k)(4). Is regulation: discharge,medical patients, or for nonpayment for his stay (except as prohibited by titles XVIII and XIX of the Social Security Act), and is given reasonable advance notice to ensure orderly transfer or discharge, and such actions are documented in his medical record;	(iii) For purpose of this procedures The term "transfer"move ment of a patient from an acute level of care to a long-term level of care within a facility, as well as, movement to another facility. "Medical reasons" for transfer or discharge are based on the patient's needs and are determined and documented by a physician. Movement may be required to provide a different level of care.	(iii) Review policies and transferred or dis- regarding charged only fortransfer and providing the patient reasons, or for his welfare and the mechanism for applies to the that of other reasonable advance notice, and verify they are implemented.

"Welfare" of a patient refers to their social or emotional well being. This is a complex concept in that assessment can vary with each individual patient, facility, and surveyor. An example of moving a patient for his welfare is to facilitate visits by relatives and friends. A patient might also be transferred or discharged because his behavior poses a continuing threat to himself (i.e., suicidal) or to the well being of other patients (e.g., his behavior is incompatible with their needs and rights).

"Reasonable advance notice" means that the decision to transfer or discharge a patient must be discussed with him, and that he be told the reasons for it and alternatives available, in advance. For moves of a patient from one location to another within the facility, the patient should be given at least 24 hours advance notice--so that he may make his wishes known and participate in the planning for the move.

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(iv) 405.1121(k)(7). Is free from mental and physical abuse and free from chemical and (except in emergencies) physical restraints except as authorized in writing by a physician for a specified and limited period of time, when necessary to protect the patient from injury to himself or to others.	(iv) Mental abuse includes, but is not limited to, humiliation, harrassment, and threats of punishment or deprivations. Physical abuse refers to corporal punishment and the use of restraints as a punishment. Drug such as tranquilizers may not be used to limit or control patient behavior for the convenience of staff ('405.1124(h)). Physican restraint includes the use of such devices as posey belts, wrist or ankle cuffs, blanket restraints, bed nets, and prolonged confinement to a geriatric chair. Physical restraints are not to be used to limit patient mobility for the convenience of staff, and must comply with life safety requirements. If a patient's behavior is such that it will result in injury to himself or others and any form of physical	(iv) Review policies and procedures regarding physical abuse and verify that they are being followed. Observe and talk with patients to determine whether they: o Feel free to relate complaints or abuses; o Seem open and secure in talking about their treatment as individuals; and o Are fearful or unwilling to assess how they are treated. Review policies and procedures governing physical restraints. Determine that: o Orders indicate the specific reasons for the use of restraints. o Their use is temporary and the patient will not be restrained for indefinite period of time;

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	restraint if utilized, it should be in conjunction with a treatment procedure designed to modify the behavioral problems for which the patient is restrained or, as a last resort, after failure of attempted therapy.	o Orders for restraints shall not be enforced for longer than 12 hours, unless warranted by the patient's condition; o A patient placed in the restraint shall be checked at least every 30 minutes by appropriately trained staff and an account is kept of this surveillance; o Reorders are issued only after a review of the patient's condition; o Their use is not employed as punishment, for the convenience of the staff, or as a substitute for supervision; o Mechanical restraints avoid physical injury to the patient and provide a minimum of discomfort; o The opportunity for motion and exercise is provided for a period of not less than 10 minutes during each 2 hours in which restraints are employed, except at night; and

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		o The practice of locking patients in their rooms or using locked restraints (also constitutes physical restraints) is in conformance with the requirements of the Life Safety Code. o Identify patients who are under restraints. Verify that the appropriate procedures are followed.
(v) 405.1121(k)(8). Is assured confidential treatment of his personal and medical records, and may approve or refuse their release to any individual outside the facility, except, in cases of his transfer to another health care institution, or as required by law or third party payment contract;		(v) Determine that the facility limits access to any medical records to staff and consultants providing professional service to the patient. ('405.1132(b)). This is not meant to preclude access by representatives of State and Federal regulatory agencies. Review procedures intended to safeguard the confidentiality of patient's personal records (e.g., financial records and social services records)and verify that only those personnel concerned with fiscal affairs of the patients have access to the financial records.

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(vi) 405.1121(k)(10). Is not required to perform services for the facility that are not included for therapeutic purposes in his plan of care;		(vi) Determine that any patient doing work for the facility does so: o Voluntarily; o With the approval of the physician; and o In accordance with therapeutic goals and professional supervision as specified in the plan of care.
(vii) 405.1121(k)(11). May associate and communicate privately with persons of his choice, and send and receive his personal mail unopened, unless medically contraindicated (as documented by his physician in his medical record);		(vii) Review visiting policies to verify that: o They are subject to reasonable scheduling restrictions, and permit patients to receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons: The patient refuses to see the visitor. The patient's physician documents specific reasons why such a visit would be harmful to the patient's health.

The visitor's behavior is unreasonably disruptive of the functioning of the facility. (This judgment must be made by the administrator and the reasons are documented and kept on file).

- o Decisions to restrict a visitor are reviewed and reevaluated each time the patient's plan of care and medical orders are reviewed by the physician and nursing staff or at the patient's request.

- o Space is provided for patients to receive visitors in reasonable comfort and privacy. Verify by talking with patients that their personal mail is sent and received unopened and that arrangements are made to provide assistance to patients who require help in reading or sending mail. Determine that telephones are available and accessible for patients to make and receive calls.

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(viii) 405.1121(k)(13). May retain and use his personal clothing and possessions as space permits, unless to do so would infringe upon rights of other patients, and unless medically contraindicated (as documented) by his physician in his medical record); and		(viii) Review the policy identifying the kinds and amounts of personal clothing and possessions patients may keep and use. Verify that this policy is implemented and is not restrictive. Verify that any personal clothing or possessions retained by the facility for the patient during his stay are identified and recordedonadmissio and a receipt given to patient. The facility is responsible for secure storage of such items. Verify that they are returned to the patient promptly upon request upon discharge from the facility.
(ix) 405.1121(k)(14). If married, is assured privacy for visits by his/her spouse; if both are inpatients in the facility, they are permitted to share a room, unless medically contraindicated (as documented by the		(ix) Verify whether there is a method for arranging for private visits between spouses. Talk to patients to determine if the policy is implemented. Verify that there is a policy which permits attending physician in married patients to the medical record). share a room and that thepolicyis implementrd

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(2) Specialized rehabilitative services (§ 405.1126). The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by patients to improve and maintain functioning. These the written order of the patient's attending physician. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain patients in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibilities for the services rendered. (See §405.1121(i)).		(2) Specialized rehabilitative services (§405.1126). Determine that the space, facilities and equipment for the service are conducive to the safe and effective care of the patient. o Verify that the area is easily accessible to patients requiring such services and that adequate space is provided. services are provided o Determine that equipment is periodically inspected and maintained. o Determine that services are provided upon written order of an attending physician. If the services are provided under an agreement with an outside agency, determine that there is a written agreement signed by the administrator and therapist. Ascertain that reference is made to the: o Delineated responsibilities of both parties;

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therapist;		o Required qualifications of the o Reponsibilities for supplies, equipment, and maintenance; o Time limit of agreement; and o Stated amount and method of remuneration.
(i) §405.1126(a). Organization and staffing. Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists. Other rehabilitative services also may be provided, but must rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and	Qualified therapists means: o Occupational therapist (qualified consultant). A person who: - Is a graduate of an occupational therapy curriculum accredited jointly by the Council on Medical Education of the American Medical Association and the American Occupational Therapy Association; or - Is eligible for certification by the American Occupational Therapy Association under its requirements in effect on the publication of this provision; or	(i) Organization and staffing. Review a facility's administrative policies to ascertain that there is an effective organizational structure which facilitates the achievement of service objectives. At least a brief statement is contained in the policy about the following areas: o Whether the services are provided directly or through written agreement; o Service objectives are identified

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assigns duties appropriate to the training and experience of those providing such services. Written administrative and patient care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs.	- Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking initial qualifications as an occupational therapist after December 31, 1977. o Physical therapist (qualified consultant). A person who is licensed as a physical therapist by the State in which practicing, and - Has graduated from a physical therapy curriculum approved by the American Physical Therapy Association, or by the Council on Medical Education and Hospitals of the American Medical Association, or jointly by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or - Prior to January 1, 1966, was admitted to membership by the American Physical Therapy Association, or American Registry of Physical Therapists, or has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or	with specific outcome; o Provisions for coordinating these services with other services are identified in the patient care plan; o Authority is delegated to carry out these responsibilities in line with the qualifications set forth; o The responsibility of the patient's physician and other required specialized personnel for participating in the overall patient care plan; o Appropriate channels of communication to route recommendations for services improvements; o Consultation; o Provisions for an effective follow-up program. Determine if the staff has the policies and is aware of their content through discussion with them. Determine that each service is staffed by sufficient personnel to respond to the specialized rehabilitative needs of the patient population being

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	- Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, except that such determinations of proficiency shall not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or - Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring physicians; or - If trained outside the United States, was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy; meets the requirements for membership in a member organization of the World Confederation for Physical Therapy; has 1 year of experience under the	served. These personnel serve under the direction of a qualified professional. Verify that a qualified professional: o Evaluates the patient, initiates the treatment, reevaluates the patient at least every 30 days; and o Provides regular supervision of the operation of the service and performance of the staff.

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	supervision of an active member of the American Physical Therapy Association; and has successfully completed a qualifying examination as prescribed by the American Therapy Association. o Speech Language Pathologist or Audiologist (Qualified Consultant): A person who is licensed, if applicable, by State in which practicing, and - Is eligible for certificate of clinical competence in the appropriate area (speech pathology or audiology) granted by the American Speech and Hearing Association under its requirements in effect on the publication of this provision; or - Meets the educational requirements for certification, and is in the process of accumulating the supervised experience required for certification.	
(ii) §405.1126(b) Plan of care. Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. Therapy is provided only upon written orders of the attending physician. A		(ii) Plan of care. Review the plan of care. Review the patient records. Determine that it: o Evaluates the extent of participation of the health team in the planning of total patient care;

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report of the patient's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. The patient's progress is thereafter reviewed regularly, the plan of rehabilitative care is reevaluated as necessary but at least every 30 days, by the physician and the therapist(s).		o Has written orders initiated by the attending physician, after consultation with the appropriate therapist; o Contains modality, duration, and frequency of treatment. Review the patient's medical record to document whether the written plan is being implemented appropriately. Ascertain that the medical record: o Contains clinical data of assessment of the patient's functional ability, etc., and a record of the patient's response to therapy; o Indicates the degree of rehabilitative nursing care activities provided as well as the specific rehabilitation services; and

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		o Shows that the plan has been reevaluated and updated as required.
(iii) §405.1126(c) Documentation of services. The physician's orders, the plan of re-habilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.		(iii) Documentation of services. Review the patient's records and other reports that are required, for evidence that: o Reports and records are complete and include baseline clinical data from initial evaluation, i.e., tests and measurements of strength, balance, endurance, range of motion, electrical myoneural responses, as well as, discharge status, including plans for continued care with instructions given to the patient and his family, if applicable; o All reports are signed by the person providing therapy and the physicians ordering the service; and o Dates are indicated on all reports as to when therapy was performed and when the results were reported to the attending physician.

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(3) Dental services (§405.1129) The facility has satisfactory arrangements to assist patients to obtain routine and emergency dental care. (See (§405.1121(i).) (The basic Hospital Insurance Program does not cover the services of a dentist in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)		(3) Dental services (§405.1129).
(i) §405.1129(a). Advisory dentist. An advisory dentist participates in the staff development program for nursing and other appropriate personnel (see ('405.1121(b)), and recommended oral hygiene policies and practices for the care of patients.		(i) Advisory dentist. Verify that the advisory dentist provides consultation in oral hygiene to the staff. Determine if recommendations from advisory dentists are implemented by interviewing the staff.
(ii) §405.1129(b). Arrangements for outside services. The facility has a cooperative agreement with a dental service, and maintains a list of dentists in the community for patients who do not have a private dentist. The facility assists the patient, if necessary, in arranging for transportation to and from the dentist's office.		(ii) Arrangements for outside services. Review the agreement for the provision of dental services. Verify that the facility has a list of community dentists available and that arrangements are made for patient transportation and appointments.

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(4) Social services (§405.1130). The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the patient. It is not mandatory that the facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring patients in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each patient to adjust to the social and emotional aspects of his illness, treatment, and stay in the facility.		(4) Social services (§405.1130). The facility does not have to provide social services, but it must have provisions for the identification of medically related social needs and arrangements for meeting these needs. To verify that the facility fulfills this requirement, Standards (a) and (c) must be surveyed.
(i) §405.1130(a). Social service functions. The medically related social and emotional needs of the patient are identified and services provided to meet them, either by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies. If financial assistance is indicated, arrangements are made promptly for referral to		(i) Social service functions. Review manual to determine if it includes a statement of the range of social services to be provided. Review a sampling of the medical records for evidence of the identification of medically related social needs and that the needs were met either directly or by referral.

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an appropriate agency. The patient and his family or responsible person are fully informed of the patient's personal and property rights.		Determine that the social and emotional needs related to the patient's illness, response to treatment, and adjustment to care in the facility are identified and included in the patient care plan. Determine that the patient's family and home situation, information related to his medical and nursing requirements, and community resources are considered in making decisions regarding his care. Determine that contact is maintained with the family about the patient's problems and rights.
(i) §405.1130(b). Staffing. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services. If the designated person is not a qualified social worker, the	(ii) Staffing. Qualified social worker means: A person who is licensed, if applicable, by the State in which practicing, is a graduate of school of social work accredited or approved by the Council on Social Work Education,	(ii) Staffing. Verify that the designated staff member is qualified, and if not, that a person so qualified provides consultation under a written agreement on a regularly scheduled basis.

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facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See§405.1121 (I).) The social service also has sufficient personnel to meet patient needs. Facilities are adequate for social service personnel, easily accessible to patients and medical and other staff, and ensure privacy for interviews.	and has 1 year of social work experience in a health care setting.	Determine if staff is sufficient to render the social service program provided by the facility. (The adequacy of personnel is determined by appropriate and timely actions, sufficient follow-ups, coordination and consultation required by other services, etc.)
(iii) §405.1130(c). Records and confidentiality of social data. Records of pertinent social data about personal and family problems medically related to the patient's illness and care, and of action taken to meet his needs, are maintained in the patient's medical record. If social services are provided by an outside resource, a record is maintained of each referral to such resource. Policies and		(iii) Records and confidentiality of social data. Review the social services policies and procedures to ascertain that they at least cover: o Type of social data to be obtained; o Confidentiality of social data, and that the patient's written consent (or that of responsible person

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procedures are established for ensuring the confidentiality of all patients' social information.		acting on his behalf) is obtained before social information is transmitted to an outside agency or individual. The consent form is filed in the patient's medical record. o Availability of data to other services; and o Transmittal of data on referral. Check that the medical records include pertinent social data of patient and family such as evaluation of needs, attitudes, feelings, and problems of the patient and family, social history and background information, and recommendations for social treatment, if necessary.
(5) Patient Activities (§405.1131). The facility provides for an activities program, appropriate to the needs and interests of each patient, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psycho-social functioning.	(5) Patient Activities (§405.1131). The purpose of an activities program is to create an environment that is as near to normal as possible, thereby encouraging persons in a facility to exercise their abilities.	(5) Patient Activities (§405.1131). Determine that the activities program provides physical, intellectual, social, spiritual and emotional challenges much the same way that everyday life in the community provides challenges. It provides these challenges in a planned, coordinated, and structured manner and the activities provided are beneficial in overcoming specific problems.

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(i) §405.1131(a). Responsibility for patient activities. A member of the facility's staff is designated as responsible for the patient activities program. If he is not a qualified patient activities coordinator, he functions with frequent, regularly scheduled consultation from a person so qualified (See §405.1121(i)).	(i) Responsibility for patient activities. A qualified patient activities coordinator (qualified consultant is a person who: o Is a qualified therapeutic recreation specialist; or o Has 2 years experience in a social or recreational program within the last 5 years, 1 year of which was full-time in a patient activities program in a health care setting; or o Is a qualified occupational therapist or occupational therapy assistant. If the designated staff member is not a qualified patient activities coordinator consultant is required. The frequency of consultation depends on the quality of the activities program. Consultation could range from weekly to semi-annually, depending on how well the interests and needs of the patients are met, and the qualifications and experience of the activities coordinator.	(i) Responsibility for patient activities. Review the qualifications of the person responsible for patient activities to verify that they meet the qualifications, or if not, that there is consultation from a person so qualified. Review the job description of the activities coordinator to verify that the responsibilities assigned are appropriate to develop the patient activities program and are commensurate with qualifications. Review the reports of the consultant and determine the adequacy of the consultation in terms of the overall quality of the activities provided and their relationship to patients' interests and needs rather than the number of consultant visits. Review the amount of time spent by the designated staff member in the patient activities program to determine adequacy.

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(ii) §405.1131(b). Patient activities program. Provision is made for an ongoing program of meaningful activities appropriate to the needs and interests of patients, designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any. Each patient's activities program is approved by the patient's attending physician as not in conflict with the treatment plan. The activities are designed to promote the physical, social, and mental well being of the patients. The facility makes available adequate space and equipment to satisfy the individual interests of patients. (See §405.1134(g)).		(ii) Patient activities program. Verify that there is a plan for each resident identifying his interests, needs, physician's recommendations, and methods for implementing plan. Documentation of this is obtained from the patient's care plan and medical record. Interview informally both bedfast and ambulatory patients to determine that they are not forced to participate in specific activities (e.g., religious services bingo). Evaluate the appropriateness of activities including weekend activities. Review the activities schedules (past and planned) to determine the nature and frequency of activities and to assure that they include provisions for religious activities, etc. Interview the activities coordinator to determine how he learns of those patients with restricted or modified activities and new patients.

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		Observe the participation of the patients in activities to verify that the program is followed. An activities schedule of special events and group activities is maintained for review by the administrator and director of nursing and is available to patients. The schedule identifies the location of the activity and the leader. Observe the activity area to determine adequacy of funds for supplies and equipment. Review medical records to document resident's participation and response and assure that the activities plan is periodically revised to reflect interests and needs. Verify that space is adequate and that an area for consultation is available for those patients who desire a private visit from the clergy, family, social worker, and others.

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		Determine if patients are assisted to attend religious services, if requested. Also, determine that patients' requests to see their clergymen are honored and appropriate arrangements are made to ensure privacy during visits. Verify that daily visiting hours are flexible, a visiting area is provided, and visiting hours are posted for the public.
(6) Discharge planning (§405.1137(h)). The facility maintains a centralized, coordinated program to ensure that each patient has a planned program of continuing care which meets his postdischarge needs.	(6) Discharge planning (§405.1137(h)). Discharge planning includes preparing the patient for the next level of care and arranging for appropriate placement (i.e., home, ICF hospital). Information needed for discharge planning process includes:	(6) Discharge Planning (§405.1137(h)).
(1) The facility has in operation an organized discharge planning program. The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the patient may be referred.	Prior health status of the patient; diagnosis; functional status; medical orders; therapy (ies) and teaching needs; current level of care needed; projected time frame for moving patient to next level of care; community resources available; and procedures for initiating and effecting transfer to other levels of care. To ensure optimal benefits, discharge planning must be a coordinated effort among the facility, the	(1) Ascertain that the facility has established an efficient discharge planning program. The program should be structured to encourage patient and family participation in setting treatment goals and establishing a long range plan of care. Each patient must

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	patient and his family, and the resource to which the patient may be discharged.	have an individual discharge plan which reflects input from all disciplines involved in his care.
(2) The administrator delegates responsibility for discharge planning, in writing, to one or more members of the facility's staff, with consultation, if necessary, or arranges for this service to be provided by a health, social, or welfare agency. (See §405.1121(i)).		(2) Determine that the administrator or his delegate is responsible for organizing the facility's discharge planning program. It is preferable that the program be facility based and coordinated by a staff member who gives full-time or part-time to the function depending upon the needs for this service. If the facility is unable to designate a responsible staff person, arrangements are made with an outside resource. When an outside resource is used, a memorandum of agreement is developed which describes the responsibilities of the two parties in developing and carrying out explicit discharge planning procedures.

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(3) The facility maintains written discharge planning procedures which describe (i) how the discharge coordinator will function, and his authority and relationships with the facility's staff; (ii) the time period in which each patient's need for discharge planning is determined (preferably within 7 days after the day of admission); (iii) the maximum time period after which a re-evaluation of each patient's discharge plan is made; (iv) local resources available to the facility, the patient, and the attending physician to assist in developing and implementing individual discharge plans; and (v) provisions for periodic review and reevaluation of the facility's discharge planning program.		(3) Review the policies and procedures to verify that they contain the following: o Functions of the discharge planning coordinator in evaluating the patient's condition to determine potential needs, in providing continuity of care and in recording results of such an evaluation; o Participation in the evaluation and planning by representatives from the pertinent disciplines; o A statement of the time period by which each patient must be evaluated in terms of discharge planning; and a statement of the time period in which each patient must be reevaluated; o A provision for making information available to the UR committee;

- o A list of local resources available;
- o Provision for review and reevaluation of the discharge planning program;
- o Orientation staff personnel to discharge planning and referral procedures and providing periodic inservice training sessions.

(4) At the time of discharge, the facility provides those responsible for the patient's postdischarge care with an appropriate summary of information about the discharged patient to ensure the optimal continuity of care. The discharge summary includes at least current information relative to diagnoses, rehabilitation potential, a summary of the course of prior treatment, physician orders for the immediate care of the patient and pertinent social information.

(4) Examine a sampling of medical records (current and discharged patients), to verify that the policies and procedures are being followed.

Evaluate the written plan which describes the discharge planning program. The plan includes: (1) the person(s) or agency responsible for the function; (2) a job description of the coordinator detailing his authority, staff relationships, duties and functions, and educational or experimental

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		requirements; (3) explicit procedures for performing the function including all forms to be used for formulation of the plan, making referrals, and preparing discharge summaries; (4) a compilation of local resources (e.g., private and public Health-Welfare Agencies, Hospitals, ICFs, licensed room and board facilities, meals on wheels, home health agencies); (5) procedures for coordinating activities with the UR Committee and any other appropriate committee (e.g., patient care policies committee); (6) a provision for at least annual review of the plan by appropriate parties. Determine that discharge planning procedures include at least the following: o Referral of cases to the discharge planning coordinator;

- Identification and evaluation of the patient's functional status and medical, nursing, rehabilitation and other needs. This will generally be accomplished through review of the records, individual interviews, and team conferences;

- Documentation for developing a discharge plan for each patient which reflects input from all disciplines, as appropriate. Examples of participation include:

  - physician - determines overall treatment plan; probable length of stay, the next level of care anticipated; and orders, care and services needed;

  - dietitian - provides teaching and consultation to patient and/or family; provides sample diets where appropriate;

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- pharmacist -
prepares the drug profile to accompany the patient and/or family in administration of drugs, where appropriate;

- nurse -
assesses the patients' nursing and health needs and provides information about these needs; provides appropriate instruction to patients and/or family;

- therapist -
develops treatment plan in tandem with physician; teaches patient and family; informs coordinator of sources for procuring equipment and supplies.

o Multidisciplinary team conferences

o Initiating referrals

o Maintaining liaison with the UR committee

- Preparing comprehensive patient care summaries for transmittal with the patient upon discharge to assure continuity of care. Use of a discharge summary form is encouraged. Ascertain that the form captures at least the following items: Identifying information (e.g., name, address, D.O.B., Medicare number, Medicaid number); next of kin or sponsor; final diagnosis; medication and treatment orders; appropriate laboratory and X-ray reports; functional capacity; special instructions (e.g., patient cannot smoke unattended); level of care needs; and summary of overall plan of care developed by multidisciplinary teams under c above.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 750	**§482.13 Condition of participation: Patients' rights.** A hospital must protect and promote each patient's rights.	Interpretive Guidelines: §482.13. These requirements apply to all Medicare or Medicaid-participating hospitals including short-term, psychiatric, rehabilitation, long-term, children's and alcohol-drug, whether or not they are accredited. This rule does not apply to psychiatric facilities for individuals under age 21, to residential treatment centers (unless these services are provided in a hospital setting); nor to Critical Access Hospitals (See Social Security Act (the Act) §1861(e)).
A 751	**(a) Standard: Notice of rights.** (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.	This regulation requires that whenever possible, the hospital informs each patient of his or her rights in language that the patient understands. The hospital has the responsibility to establish policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights under the Act. This responsibility includes and is not limited to providing all notices required by statute and regulation regarding patients' rights. For example, the patient must be given notice of the rights afforded to him/her by the provider agreement, including the right to an advance directive and notice of non-coverage (see 42 CFR part 489), as well as the rights listed in this CoP. Depending on other factors, the hospital may have existing mechanisms for notifying patients of their rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices. In providing this information, the hospital must be sensitive to the communication needs of its patients. As part of its provider agreement, the hospital agrees to comply with Civil Rights laws that assure that it will provide interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient. These civil rights laws and regulations also apply to the provision of this information. The hospital's obligation to inform requires that the hospital presents information in a manner and form that can be understood, e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters. The regulation does not require documentation in the patient's record that this information has been provided. For example, as part of its admission procedure, the hospital may routinely provide this information with each admission packet. The method for achieving notification of patients rights and whether this is documented is determined by the hospital.

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A 751 Cont.		Procedures: §482.13(a)(1) 1. Determine the hospital's policy for notifying patients of their rights. 2. Review records and interview staff to examine how the hospital meets the needs of diverse patients. 3. Individuals who need assistive devices (e.g., magnifying glass, braille, sign language), or have a communications challenge, such as deafness, low vision, blindness, or not being proficient in English, are at risk of not being informed of their rights. Include in the patient sample current patients who use assistive devices. Interview these patients, and/or their representatives to determine how the hospital assures that patients with these needs have been informed of their rights in a language and manner they understand. Probes: §482.13(a)(1) 1. Does the hospital have alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary? 2. Do staff know what steps to take to inform a patient, if a patient has special needs?
A 752	(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.	Interpretive Guidelines: §482.13(a)(2) A "patient grievance" is a formal, written or verbal grievance that is filed by a patient, when a patient issue cannot be resolved promptly by staff present. The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although §482.13(a)(2)(ii) and (iii), A756 and A 757, address documentation of facility time frames for a response, the expectation is that the facility will have a process to implement a relatively minor change in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverages may be made relatively quickly without a written facility response. The hospital must inform the patient of the grievance process; including whom to contact to file a grievance. The hospital must inform the patient that he/she may lodge a grievance with the State agency directly, regardless of whether he/she has first used the hospital's grievance process. The hospital must further provide the patient a phone number and address for lodging a grievance with the State agency.

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A 752 Cont.		Procedures: §482.13(a)(2) 1. Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. 2. Interview patients or the patient's legal representative to determine compliance. Probes: §482.13(a)(2) 1. Is the hospital following its grievance policies and procedures? 2. Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner? 3. Does the patient know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?
A 753	The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.	Procedures: §482.13(a)(2) 1. Determine how effectively the grievance process works. Are patient concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities? Probes: §482.213 (a)(2) 1. Is the governing body responsible for this function, or has the governing body delegated the responsibility in writing to a grievance committee? 2. Is the grievance process reviewed and analyzed through the hospital's quality assurance process or some other mechanism that provides oversight of the grievance process?
A 754	The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization. At a minimum:	Interpretive Guidelines: §482.13(a)(2) This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to peer review organizations (PROs) for Medicare beneficiary concerns (see 42 CFR part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the PRO; however, the hospital must inform the beneficiary of this right and comply with his or her request if the beneficiary asks for PRO review.
A 755	(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.	Interpretive Guidelines: §482.13(a)(2)(i) A grievance may be filed verbally or in writing. Probe: §482.13(a)(2)(i) 1. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to use it?

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A 756	(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.	Interpretive Guidelines: §482.13(a)(2)(ii) The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.
A 757	(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.	Interpretive Guidelines: §482.13(a)(2)(iii) The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative, when necessary, understands. The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family, or other methods it finds effective. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances.
A 758	**(b) Standard: Exercise of rights.** (1) The patient has the right to participate in the development and implementation of his or her plan of care.	Interpretive Guidelines: §482.13(b)(1) This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient's care, with patient participation, to meet the patient's psychological and medical needs. Procedures: §482.13(b)(1). 1. Determine the extent to which the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care. 2. If the patient refused to participate, interview the patient to verify his/her refusal. Probes: §482.13(b)(1) 1. What do you observe about the interactions between staff and patients? 2. Is there evidence that the patient or the patient's legal respresentative was included or proactively involved in the development of the patient's plan of care? 3. Were revisions in the plan of care explained to the patient?
A 759	(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.	Interpretive Guidelines: §482.13(b)(2) A patient may wish to delegate decision-making to specific persons, or the patient and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the

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A 759 Cont.		patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital should consult the patient's advance directives (see discussion at A 761). In the advance directive, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, relevant information should be provided to him/her so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient. This regulation stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary. Procedure: §482.13(b)(2) 1. Review records to determine what happens when staff and a patient disagree regarding the patient's plan of care. Probes: §482.13(b)(2) 1. Does evidence indicate the hospital respected a patient's request for or refusal of certain treatments?
A 760	The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.	Probes: §482.13(b)(2): 1. Has the patient been notified of his/her right to: a. Be informed of his/her health status; b. Be informed of his/her prognosis; c. Be involved in care planning and treatment, including pain management; and d. Request or refuse treatment? 2. Does evidence indicate that a patient's request for treatment was denied? If so, what was the reason for that denial?
A 761	(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).	Interpretive Guidelines: §482.13(b)(3) 42 CFR part 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions (e.g., pain managment) and to formulate an advance directive and requires the hospital to do the following: ■ Disseminate its policies regarding the implementation of advance directives, including a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

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A 761 Cont.		o Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians; o Identify the State legal authority permitting such an objection; and o Describe the range of medical conditions or procedures affected by the conscience objection. ■ The hospital must: o Document in the patient's medical record whether or not the patient has executed an advance directive; o Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; o Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency; and o Provide for the education of staff concerning its policies and procedures on advance directives. Procedures: §482.13(b)(3) 1. Review the records of a random sampling of patients for evidence of hospital compliance with advance directive notice requirements. 2. Interview staff to determine their knowledge of the advance directives of the patients in their care. 3. Determine to what extent the hospital educates its staff regarding advance directives. 4. Determine to what extent the hospital provides education for the patient population regarding one's rights under State law to formulate advance directives.
A 762	(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.	Probes: §482.13(b)(4) 1. Is there evidence that the hospital has a system in place to assure that a patient's family and physician are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done)?
A 763	**(c) Standard: Privacy and safety.** (1) The patient has the right to personal privacy.	Interpretive Guidelines: §482.13(c)(1) The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" means that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate.

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A 763 Cont.		People not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. Privacy should be afforded when the physician or other staff visit the patient to discuss clinical care issues. A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm self (such as when the patient is under suicide precautions) or others exists.
A 764	(2) The patient has the right to receive care in a safe setting.	Interpretive Guidelines: §482.13(c)(2) The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. (In situations related to harassment and/or abuse see A765). Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment. Procedures: §482.13(c)(2) 1. Review and analyze patient and staff incident and accident reports prior to the survey to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospital. 2. Review QA/QI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment. 3. Observe the environment where care and treatment are provided. 4. Review policy and procedures on what the facility does to curtail unwanted visitors or contraband materials.
A 765	(3) The patient has the right to be free from all forms of abuse or harassment.	Interpretive Guidelines: §482.13(c)(3) The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors. Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another.

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A 765 Cont.		For the purpose of this requirement, neglect is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. Procedures: §482.13(c)(3) Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, or visitors. In particular, determine the extent to which the hospital includes the following components that are suggested as necessary for effective abuse protection: (1) Prevent. A critical part of this system is that there are sufficient staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (2) Screen. Persons with a record of abuse or neglect should not be hired or retained as employees. (3) Identify. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect. (4) Train. The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection. (5) Protect. The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment. (6) Investigate. The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment. (7) Report/Respond. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial, or disciplinary action occurs, in accordance with applicable local, State, or Federal law. As a result of the implementation of this system, changes to the hospital's policies and procedures are made accordingly. Probes: §482.13(c)(3) 1. Are staffing levels across all shifts sufficient to care for individual patient's needs? 2. Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations? 3. How does the hospital substantiate allegations of abuse and neglect? 4. Do incidents of substantiated abuse and neglect result in appropriate action? 5. Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect? 6. Do staff members know what to do if they witness abuse and neglect?

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A 765 Cont.		7. What evidence is there that allegations of abuse and neglect are thoroughly investigated? If substantiated, has the hospital taken corrective action to lower the risk of recurrence? 8. Does the hospital conduct criminal background checks as allowed by State law for all potential new hires? 9. Is there evidence the hospital employs people with a history of abuse, neglect or harassment?
A 766	**(d) Standard: Confidentiality of patient records.** (1) The patient has the right to the confidentiality of his or her clinical records.	Interpretive Guidelines: §482.13(d) The hospital has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual. Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.
A 767	(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame.	Interpretive Guidelines: §482.13(d)(2) The general position of the Department of Health and Human Services with regard to the confidentiality rights of individuals is set forth in "Confidentiality of Individually-Identifiable Health Information, recommendations of the Secretary of Health and Human Services, pursuant to §264 of the Health Insurance Portability and Accountability Act of 1996." That policy specifies that patients should be allowed to inspect and obtain a copy of health information about themselves that is held by providers; and that providers may not withhold information except under limited circumstances. These circumstances include: o The information is about another person (other than a health care provider) and the hospital determines that patient inspection would cause sufficient harm to another individual to warrant withholding. o Inspection could be reasonably likely to endanger the life or physical safety of the patient or anyone else. o The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source.

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A 767 Cont.		o The information is held by an oversight agency and access by the patient could be reasonably likely to impede an ongoing oversight or law enforcement activity. o The information is collected in the course of a clinical trial, the trial is in progress, an institutional review board has approved the denial of access, and the patient has agreed to the denial of access when consenting to participate. o The information is compiled principally in anticipation of, or for use in, a legal proceeding. o The information is used solely for internal management purposes and is not used in treating the patient or making any administrative determination about the patient, or if it duplicates information available for inspection by the patient. Probes: §482.13(d)(2) 1. Does the hospital have a procedure for providing records to patients within a reasonable timeframe? 2. Does the procedure include the method to identify what documents were not provided and the reason?
A 768	The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.	Interpretive Guidelines: §482.13(d)(2) In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified in A767. In these cases, the record holder may decide to withhold portions of the record; however, to the extent possible, the patient should be given as much information as possible. If the patient is incompetent, the patient record should be made available to his or her representative (as allowed under State law). Upon the patient's request, other designated individuals may access the patient's records. The patient has the right to easily access his/her medical records. The cost of duplicating a patient's medical record must not create a barrier to the individual's receiving his or her medical records. Records should be supplied at a cost not to exceed the community standard. If State law establishes a rate for the provision of records, then State law should be followed. However, in the absence of State law, the rate charged by organizations such as the local library, post office, or a local commercial copy center that would be selected by a prudent buyer can be used as a comparative standard.
	The following guidelines apply to both standard "e" and standard "f".	

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		Standards (e) and (f) concern the use of restraints in two situations: respectively, standard (e), use of restraints in medical and post-surgical care; and standard (f), **emergency use** of restraints in behavior management. For both situations, it is important to note that these requirements are not specific to any treatment setting, but to the situation the restraint is being used to address. Further, the decision to use a restraint is driven not by diagnosis, but by comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures poses a greater risk than the risk of using a restraint or seclusion. In the case of a patient with cognitive impairment, such as Alzheimer's Disease, which restraint standard (e) or (f) would apply? Two examples are offered for the sake of clarification. o Example 1: A patient with Alzheimer's Disease has a catastrophic reaction where he/she becomes so agitated and aggressive that he/she physically attacks a staff member. He/she cannot be calmed by other mechanisms, and his/her behavior presents a danger to himself, and to staff and other patients. The use of restraint or seclusion in this situation is governed by the behavior management standard. o Example 2: A patient diagnosed with Alzheimer's Disease has surgery for a fractured hip. Staff determine that it is necessary to immobilize the hip to prevent re-injury. The use of less restrictive alternatives have been evaluated or were unsuccessful. Restraint use in this situation is governed by the acute medical and surgical care standard (§482.13(e)). Comprehensive assessment is critical in coming to an effective intervention decision of what would be the greater benefit to a patient. In the case of a patient with dementia who wanders and there is concern about the patient falling, part of the hospital's assessment process should address these questions: o Is there a way to enable the patient to ambulate safely? o Is there some assistive device that will improve the patient's ability to safely self ambulate? o Is a medication or a reversible condition causing a problem with safely self ambulating? o Would the patient be content to walk with a staff person for a while? o Could he/she be brought closer to the nurse's station where he/she could be supervised? o Does he/she have a history of falling that indicates that for him/her, a fall is likely if he/she is allowed to walk about? o Could the patient's environment be altered to improve the patient's ability to self ambulate and reduce the risk of falling/injury?

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		Licensed Independent Practitioner (LIP) For the purpose of this rule, a LIP is any practitioner permitted by both law and the hospital as having the authority under his/her license to independently order restraints, seclulsion or medications for patients. This provision is not to be construed to limit the authority of a doctor of medicine or ostepathy to delegate tasks to other qualified healthcare personnel (i.e., Physician Assistants and Nurse Practioners) to the extent recognized under State law or a State's regulatory mechanism. Exceptions: The use of handcuffs or other restrictive devices applied by law enforcement officials is for custody, detention, and public safety reasons, and is not involved in the provision of health care. Therefore, the use of restrictive devices applied and monitored by law enforcement are not governed by standards (e) or (f) of the regulation. A voluntary mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint. A positioning or securing device used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint. Devices Which Serve Multiple Purposes Devices which serve multiple purposes such as a gerichair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint. Use of these restraints are not typically used to address violence or aggression, therefore their use would be governed by standard (e). The hospital should base its assessment for device use on what constitutes the least risk for the patient: the risk of what might happen if the device is not used versus the risk it poses as a restraint. Evaluation of whether devices should be used as restraints must include how they benefit the patient, and whether a less restrictive device/intervention could offer the same benefit at less risk. In any case, a thorough evaluation of the patient and his/her needs is essential. It is important to note that side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bedframe and the side rail.

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		Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised siderails. Drugs Used as a Restraint Both standards (e) and (f) specify that a drug used as a restraint is a medication used to restrict the patient's freedom of movement in medical-post surgical situations (standard (e)) or for the emergency control of behavior (standard (f)), and is not a standard treatment for the patient's medical or psychiatric condition. A fundamental right that appears in both standards (e) and (f) is that the patient has the right to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by staff – including drugs that are used as restraints. Three examples serve to clarify the distinction between standards (e) and (f). o Example 1: A patient has Sundowner's Syndrome. She gets out of bed in the evening and walks around the unit. The unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to "knock out" the patient and keep her in bed. The patient has no medical symptoms or conditions that indicate that she needs a sedative. In this case, for this patient, the drug is being used inappropriately as a restraint. o Example 2: A patient is on an acute medical and surgical unit for a routine surgical procedure. He has no history of a psychiatric condition and is on no medications (aside from those he is being given before, during, and after surgery). One afternoon during his recovery period, the patient becomes increasingly agitated and aggressive. Attempts to divert and calm him are ineffective. He begins shouting that his roommate is spying on him, and physically attacks the roommate. In this case, the use of a drug as a restraint to calm and protect the patient and his roommate from harm is governed by standard (f) – seclusion and restraint for behavior management. This patient needs to be seen and assessed by a physician or LIP within one hour of the initiation of the drug used as a restraint. o Example 3: A patient is in a detoxification program. He becomes violent and aggressive one afternoon. Staff administer a PRN medication ordered by the patient's physician or LIP to address this outburst of specific behaviors. In this case, the medication used for this patient is not considered a "drug used as a

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		restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as, of aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is "a standard treatment for his medical or psychiatric condition." The use of this medication for this patient is not affected by standard (e) or (f). Drugs used as restraints are medications used in addition to or in replacement of the patient's regular drug regimen to control extreme behavior during an emergency. The medications that comprise the patient's regular medical regimen (including PRN medications) are not considered drug restraints, even if their purpose is to control ongoing behavior. The use of this medication should be addressed in the patient's plan of care and medical record. <u>Physical Restraint</u> The definition of physical restraint is any manual method or physical or mechanical device that restricts freedom of movement or normal access to one's body, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove. Holding a patient in a manner that restricts his/her movement constitutes restraint for that patient. An object may be a restraint by functional definition; that is, when an object restricts the patient's movement or access to his or her body, it is a restraint. Under this definition, all sorts of more commonly used hospital devices and practices could meet the definition of a restraint, such as: -- Tucking a patient's sheets in so tightly that he or she cannot move; or -- Using a side rail to prevent a patient from voluntarily getting out of bed. The following questions need to be considered when defining an intervention as a physical restraint. -- Does the patient have the ability/skill to easily remove the intervention? AND -- Is the patient's freedom to move when the intervention is in place less than their freedom to move without the intervention, or is the patient's access to their body when the intervention is in place less than their access to their body without the intervention? A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

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A 768 Cont.		Who is Authorized to Remove a Restraint? The hospital should address in its policies and procedures, at a minimum: o who has the authority to discontinue restraints (based on state law and hospital policies); and o under what circumstances restraints are to be discontinued.
A 769	**(e) Standard: Restraint for acute medical and surgical care**	Interpretive Guidelines: §482.13(e) In acute medical and post surgical care, a restraint may be necessary to ensure that (for example) an intravenous (IV) or feeding tube will not be removed, or that a patient who is temporarily or permanently incapacitated with a broken hip will not attempt to walk before it is medically appropriate. That is, medical restraint may be used to limit mobility, temporarily immobilize a patient related to a medical, post-surgical or dental procedure. If the intervention is undertaken because of an unanticipated outburst of severely aggressive or destructive behavior that poses an imminent danger to the patient or others, standard (f) applies. Other uses of restraint for acute medical and post-surgical care should be considered under standard (e). Risks associated with any intervention must be considered in the context of an ongoing loop of assessment, intervention, evaluation, and reintervention. A corollary principle is that the greater the risks associated with an intervention, the more careful and thorough the assessment must be. The rationale that the patient should be restrained because he/she "might" fall is an inadequate basis for using a restraint. When assessing and care planning for the patient, the hospital should consider whether he/she has a history of falling or a medical condition or symptom that indicates a need for a protective intervention. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. A restraint must not serve as a substitute for adequate staffing to monitor patients. Procedures: §482.13(e) 1. Obtain a random sampling of restrained patients. Are inordinate numbers of patients restrained given the hospital's patient composition at that time? 2. What evidence is there that hospital staff identified the reason for the restraint, and eliminated other less invasive measures before applying the restraint? 3. Determine if there is a pattern of increased restraint use related to staff coverage. 4. Are there patterns of applying the same type of restraint regardless of the medical condition of patients? 5. Review patient incident/accident reports to determine the frequency (percent) of injuried patients who were also restrained at the time of their injury.

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A 769 Cont.		6. If record review indicates that restrained patients sustained injuries, determine what the hospital did to prevent additional injury while it investigated possible changes to its restraint protocol. 7. Were the reasons for the use of a restraint in relation to the medical condition explained to the patient in understandable terms? Could the patient articulate his/her understanding?
A 770	(1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement, and is not a standard treatment for the patient's medical or psychiatric condition. (2) A restraint can only be used if needed to improve the patient's well being and less restrictive interventions have been determined to be ineffective. (3) The use of a restraint must be-- (i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm.	Interpretive Guidelines: §482.13(e)(2) A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but should be considered prior to the use of a restraint. Probes: §482.13(e)(2)(3)(i) 1. Is there documentation in the medical record to explain the rationale for the use of restraints? 2. Were less intrusive measures considered first?

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A 771 Cont	(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must--	Interpretive Guidelines: §482.13(e)(3)(ii) The hospital should have a written policy, conforming to state law, indicating which LIP are permitted to order restraint in that facility. Procedure: §482.13(e)(2)(3)(ii) 1. Review hospital policy and medical by-laws to ascertain clinical practice guidelines which describe the responsibilities of medical staff and clinicians who are privileged in this area. 2. Know who the State recognizes as a LIP or as having the right to order restraints or seclusion
A 772	(A) Never be written as a standing or on an as needed basis (that is, PRN); and	Interpretive Guidelines: §482.13(e)(3)(ii)(A) This regulation prohibits the use of PRN orders for restraint use. Procedures: §482.13(e)(3)(ii)(A) 1. Verify in the patient's medical record, and/or the physician's order, that the intent of the order is for the specific reason, and for the specified time period. 2. Review the medical record including the progress notes, flow charts and nursing notes to evaluate any patterns of use and if orders were obtained. Probes: §482.13(e)(3)(ii)(A) 1. Is there evidence of restraints being implemented on a PRN basis?
A 773	(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;	Interpretive Guidelines: §482.13 (e)(3)(ii)(B) The "treating" physician is the physician who is responsible for the management and care of the patient. It is important to consult with the treating physician, as soon as possible, because information regarding the patient's history may have a significant impact on selection of restraint intervention. Procedure: §482.13(e)(3)(ii)(B) 1. Check the patient's medical record for documentation of contact with the treating physician if he/she did not order the restraint.
A 774	(iii) In accordance with a written modification to the patient's plan of care;	Interpretive Guidelines: §482.13(e)(3)(B)(iii) The use of restraints (including drugs used as restraints and physical restraints) should be referred to in the patient's "modified" plan of care or treatment plan. Procedures: §482.13(e)(3)(B)(iii) 1. Determine whether the hospital's procedure followed the expectations of restraint requirements. Does the plan of care reflect a loop of assessment, intervention, evaluation, and re-intervention.

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A 774 Cont.		Probes: §482.13 (e)(3)(B)(iii) 1. Is there evidence of assessment of the identified problem or of individual patient assessment? 2. Does the patient's plan of care reflect that assessment? 3. What was the goal? Was it outcome oriented? 4. What was the described intervention? 5. Who is responsible for implementation? 6. Did the physician orders, which included a time-limit, get incorporated into the plan of care? 7. After the discontinuation of the restraint intervention, was this information documented in the update of the plan of care?
A 775	(iv) Implemented in the least restrictive manner possible.	See A 770 for guidance. The least restrictive intervention is based on an individual assessment of the patient.
A 776	(v) In accordance with safe and appropriate restraining techniques, and	Interpretive Guidelines: §482.13(e)(3)(B)(v) Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining technique in that environment. Restraint use should not cause harm or pain to the patient. Procedure: §482.13(e)(3)(B)(v) 1. Examine medical records of patients for whom restraints are used in the sample. Probes: §482.13(e)(3)(B)(v) 1. After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safely applied? 2. Was nursing procedure and policy followed? 3. What was the patient's response? If negative, were timely changes made? 4. Was there any evidence of injury to the patient?
A 777	(vi) Ended at the earliest possible time.	Interpretive Guidelines: §482.13(e)(3)(B)(vi) The use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Probes: §482.13(e)(3)(B)(vi) 1. If the time of restraint use is lengthy, look for evidence that the symptoms necessitating the restraint use have persisted. Is there evidence to indicate that the staff have evaluated if the restraint can be safely removed? 2. What are the hospital's policies and procedures for ending restraint use for medical and post surgical care?

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A 778 Cont.	(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.	Interpretive Guidelines: §482.13(e)(4) The determination of frequency of monitoring should be made on an individual basis which includes a rationale that reflects consideration of the individual patient's medical needs and health status. Hospital policies and/or nursing policies should address: frequencies of assessment; assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity); and provide for nutritional needs, range of motion, and elimination needs. Probes: §482.13(e)(4) 1. Was there a valid rationale for the decision regarding the frequency of assessment/monitoring documented in the medical record? 2. Was documentation consistent, relevant, and reflective of the patient's condition? 3. If the patient's mental status, coordination, or gait improved, what actions were taken by the staff? 4. What evidence do you find the hospital's/nursing assessment/monitoring policies are put into practice on all restrained patients? 5. Do the patient's care needs dictate how frequently the reassessment is made, and is there documented evidence of the reassessment?
A 779	(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.	Interpretive Guidelines: §482.13(e)(5) Ongoing restraint and seclusion education and training must be provided both as a part of the initial orientation of all new and contract staff and as a part of ongoing inservice training for all staff who have direct patient care responsibilities. Probes: §482.13(e)(5) 1. Does the facility have a documented educational, instructional training program for the use of all restraint techniques used? 2. Are all levels of staff who have direct patient care responsibilities trained in the proper and safe application and use of restraints? Is this documented? 3. Does the training require staff to demonstrate knowledge of the assessment loop and the safe application of restraints before they are allowed to apply restraints? 4. Does the training review alternatives to the use of restraints? 5. Do all contract/agency personnel with direct patient care responsibilities have documented training in the hospital's restraint/seclusion policies?
A 780	**(f) Standard: Seclusion and restraint for behavior management.** (1) The patient has the right to be free from seclusion and restraints, of any form,	Interpretive Guidelines: §482.13(f)(1) "Seclusion" does not include confinement on a locked unit or ward where the patient is with others. Seclusion is not just confining an individual to an area but involuntarily confining him/her alone in a room or area where he/she is physically prevented from leaving. Seclusion

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 780 Cont.	imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control the behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.	is different from timeout which means the restriction of a patient for any period of time to a designated area from which the patient is not physically prevented from leaving and for the purpose of providing the patient an opportunity to regain self-control. The behavior management standard for restraints and seclusion should be followed in emergency or crisis situations if a patient's behavior becomes aggressive or violent, presenting an immediate, serious danger to his/her safety or that of others. The behavior management standard governs the use of a restraint or seclusion in this type of a crisis situation whether it occurs on acute medical and surgical units, psychiatric units, Alzheimer's units, or in general, psychiatric, alcohol-drug, children's, rehabilitation, short-term, or long-term care hospitals. A restraint or seclusion for behavior management is used only as an emergency measure and is reserved for those occasions when severely aggressive or destructive behavior places the patient or others in imminent danger. While different factors may precipitate this type of psychiatric, behavioral, and physical outburst for an individual patient, the need for rapid assessment and continuous monitoring is applicable in each case. The behavior management standard (Standard (f)) does not apply to situations where the hospital wishes to restrain a patient to address the risk of a fall or to control wandering. The use of restraint for a non-violent or non-aggressive, otherwise cooperative patient may be governed by the Restraint of acute medical and surgical care (standard (e)). It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient nor can restraint use serve as a substitute for adequate staffing to monitor a patient.
A 781	(2) Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.	Interpretive Guidelines: §482.13(f)(2) Emergency is defined as a situation where the patient's behavior is violent or aggressive and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others. Documentation in the patient's medial record should include: - The patient's behavior and the intervention used; - The rationale for the use of the physical restraint or seclusion; and - The patient's response to the use of physical restraint or seclusion. Documentation in the patient's record should indicate a clear progression in how techniques are implemented with less intrusive restrictive interventions attempted (or considered prior to the introduction of more restrictive measures).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 781 Cont.		Procedures: §482.13(f)(2) 1. Review hospital procedures for emergency use of restraints and seclusion. 2. Look at incident and accident reports to determine if incidents and accidents are greater with restrained or secluded patients. 3. Examine patterns of restraints or seclusion use that may indicate that the intervention is not based on the patient's need, but on issues such as inadequate staffing or lack of training. Probes: §482.13(f)(2) 1. Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? 2. Do physician orders specify the reason for seclusion/restraint, the type of restraint and the duration? 3. Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others? 4. Is there evidence that the hospital considers factors other than the individual patient in determining causes for the need for restraints or seclusion (i.e., environmental factors)? 5. Does the clinical record reflect assessment and/or development of a plan of care?
A 782	(3) The use of a restraint or seclusion must be- (i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.	Probes: §482.13 (f)(3)(i) 1. Does the clinical record reflect changes in behavior and staff concerns regarding potential danger on the unit/ward prompting use of seclusion or restraints? 2. Did the patient's behavior place others/self at risk of harm? 3. Were other behavior interventions tried and documented?
A 783	(f)(3) The use of a restraint or seclusion must be-- (ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint.	Interpretive Guidelines: §482.13(f)(3)(ii) Hospitals should have policies and procedures for the initiation of restraint or seclusion to manage violent, aggressive behavior that places the patient or others in danger. This protocol should specify who can initiate restraints or seclusion in an emergency prior to obtaining a physician's or LIP's order. The use of verbal orders should be addressed. Probes: §482.13(f)(3)(ii) 1. Does the hospital have written policy indicating which practitioners are permitted to order seclusion or restraints in the facility? 2. Do the hospital's written policies conform with State law? 3. Does the hospital have written policies on the use of verbal orders? 4. Does the hospital have established policies for who can initiate restraint and seclusion? 5. Are the staff members who are able to initiate restraint and seclusion trained in the safe use of restraint and seclusion and able to demonstrate competency?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	The following requirements will be superseded by existing State laws that are more restrictive:	
A 784	(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).	Interpretive Guidelines: §482.13(f)(3)(ii)(A) Ongoing authorization of restrictive techniques is not permitted. The absence of evidence to justify such usage constitutes a "PRN order" to control inappropriate behavior, and is prohibited. Probe: §482.13(f)(3)(ii)(A) 1. Is there evidence of restraints or seclusion being implemented on a PRN basis?
A 785	(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.	Procedures: §482.13(f)(3)(B) 1. Determine the hospital's policies and procedures for prompt notification of treating physician when seclusion or restraint is ordered by someone other than the treating physician. 2. Determine if medical records reflect hospital's policies and procedures.
A 786	(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.	Interpretive Guidelines: §482.13(f)(3)(ii)(C) A physician or LIP (as recognized by State law and hospital policy) evaluation of a patient must be face-to-face. A telephone call is not adequate. If a patient who is restrained for aggressiveness or violence quickly recovers and is released before the physician or LIP arrives to perform the assessment, the physician or LIP must still see the patient face-to-face to perform the assessment within 1 hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt assessment of the incident/situation that led to the intervention, as well as the physiological and psychological condition of the patient at the time of the assessment.
A 787	(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9.	Interpretive Guidelines: §482.13(f)(ii)(D) The use of physical restraint or seclusion must be limited to the duration of the emergency safety situation regardless of the length of the order. The time frames specified in these requirements are maximums. The physician or LIP has the discretion to decide that the order should be written for a shorter period of time; and in the meantime, staff should be assessing, monitoring, and re-evaluating the patient so that he or she is released from the restraint or seclusion at the earliest possible time. If restraints or seclusion are discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating seclusion or reapplying the restraints and the requirements restart.

TAG		

NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 787 Cont.		The physician is not required to perform another face-to-face assessment of the patient after 4 hours (or 2 hours or 1 hour for younger patients). While we encourage physician or LIP participation in the delivery of care and treatment, when the original order is about to expire, a nurse can telephone the physician or LIP, report the results of his/her most recent assessment, and request that the original order be renewed for another period of time (not to exceed the time limits established in the regulation).
A 788	The original order may only be renewed in accordance with these limits for up to a total of 24 hours.	Interpretive Guidelines: §482.13(f)(ii)(D)(i) Orders for restraints must be renewed on a daily basis. Probe: §482.13(f)(ii)(D)(i) 1. Does the renewal for seclusion/restraint provide a rationale that is based on an individual assessment of the patient?
A 789	After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.	At a minimum, if the patient has been in a restraint or in seclusion for 24 hours, the physician or LIP will at that point return to complete a face-to-face reevaluation. Twenty-four hours of restraint or seclusion is an extreme measure with the potential for serious harm to the patient. Probe: §482.13(f)(3)(ii)(D)(ii) If patients are in seclusion or restraints for longer than 24 hours, is there evidence of a new written order and assessment documentation in the medical record that provides a reasonable rationale supporting the decision to continue with that intervention?
A 790	(iii) In accordance with a written modification to the patient's plan of care;	The interpretive guidance, procedures, and probes at A 774 should be used to evaluate the use of seclusion or restraint for this requirement.
A 791	(iv) Implemented in the least restrictive manner possible;	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(iv) A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint are outweighed by the risk of not using it. Alternative interventions do not always need to be tried, but should be considered prior to the use of a restraint/seclusion. Probes: §482.13(f)(3)(ii)(D)(iv) 1. Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint? That is, what documentation is in the medical record to explain the rationale for the use of restraints? 2. Were less intrusive measures tried or considered first? 3. Are those measures documented? 4. Is there evidence of consideration of the patient's health needs/problems prior to implementation of the intervention?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 792	(v) In accordance with safe appropriate restraining techniques; and	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(v) Restraint/seclusion use should not cause harm or pain to patient. Procedure: §482.13(f)(3)(ii)(D)(v) 1. Examine and include patients for whom restraint is used in the sample. 2. Determine if the hospital's procedures reflect current standards of practice regarding appropriate restraining techniques. Probes: §482.13(f)(3)(ii)(D)(v) 1. Is there a clear description of the physical intervention utilized? 2. Did staff do an immediate assessment of the patient to ensure that the restraints were safely and correctly applied? 3. Was nursing procedure and policy followed? 4. What was the patient's response? If negative, were changes made? 5. Was there any evidence of injury to the patient?
A 793	(vi) Ended at the earliest possible time.	Interpretive Guidelines: §482.13(f)(3)(ii)(D)(vi) The use of restraints/seclusion should be frequently evaluated and ended at the earliest possible time based on the assessment and reevaluation of the patient's condition. Probes: §482.13(f)(3)(ii)(D)(vi) 1. If the time of restraint use is lengthy, is there evidence that the symptoms necessitating the restraint use have persisted. 2. What are the hospital's policies and procedures for ending restraint use for behavior management? 3. Does the evidence indicate that the staff have evaluated the patient's behavior so that the restraint can safely be removed?
A 794	(4) A restraint and seclusion may not be used simultaneously unless the patient is-- (i) Continually monitored face-to-face by an assigned staff member; or	Interpretive Guidelines: §482.13(f)(4) When using both seclusion and restraints at the same time, continual monitoring is defined as uninterrupted monitoring. Probes: §482.13(f)(4)(i) 1. Does the clinical record reflect uninterrupted monitoring?
A 795	(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.	Interpretive Guidelines: §482.13(f)(4)(ii) The use of video and audio equipment does not eliminate the need for frequent assessment of the patients needs and status.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 795 Cont.		The hospital should ensure that staff who are assigned monitoring duties are competent to assess physical and psychological signs of distress. Probe §482.13(f)(4)(ii) 1. Is the staff person monitoring the patient in close proximity to the patient so as to allow emergency intervention if a problem arises? 2. Does the video equipment cover all areas of the room or location where the patient is restrained or secluded?
A 796	(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.	Interpretive Guidelines: §482.13(f)(5) The frequency of monitoring will vary according to the type and design of the device or intervention as well as the emotional, psychological and physical condition, needs, and symptoms of the patient. Procedures: §482.13(f)(5) 1. Review the hospital's policy on restraints and seclusion to determine how the facility is assessing and monitoring patient medical and behavioral status. Obtain a sample of the patient population in restraints. 2. Look for a cycle of removing restraints, then reapplying them without evaluating the patient. Probes: §482.13(f)(5) 1. Does hospital policy describe which staff members are responsible for assessing and monitoring the patient? 2. Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, skin integrity checks? 3. Does the policy include frequent opportunities for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the record? 4. Is the mental status assessed? Is this documented in the record? 5. Is the patient assessed regarding continued need for use of seclusion or restraint? Is there adequate justification for continued use and is this documented? 6. Is there documentation of ongoing patient assessment (e.g., skin integrity, circulation, respiration, intake and output, weight, hygiene, injury, etc)? 7. Did the patients understand the reasons for the use of restraints or seclusion?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A 797	(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and	Probe: §482.13 (f)(6) 1. Does the hospital have evidence that all staff who have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards, EMTs on the promises) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?
A 798	alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.	Probes: §482.13(f)(6) 1. Is there evidence that staff are updated and trained on alternative interventions other than restraint/seclusion techniques?
A 799	(7) The hospital must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.	Interpretive Guidelines: §482.13(f)(7) The hospital must report to HCFA any death that occurs while a patient is in seclusion, or where it is reasonable to assume that the patient's death is a result of being in seclusion. The hospital must report to HCFA any death that occurs while a patient is in restraints for behavioral management reasons or where it is reasonable to assume that the patient's death is a result of restraint use for behavioral management reasons. The hospital should report these deaths to their HCFA regional office by the next business day following the patient's death. Procedures: §482.13(f)(7) 1. Review the written hospital policy on reporting deaths that occur while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. 2. Interview patient care staff to determine their knowledge of the hospital's policy or protocol regarding the determination whether a death reasonably may have resulted from seclusion or restraint, and their knowledge of HCFA reporting requirements. Probes: §482.13(f)(7) 1. Is there evidence of deaths, associated with restraints or seclusion, not reported to HCFA? 2. If there have been deaths associated with seclusions or restraints, were they reported to HCFA in a timely manner? Was this documented in the medical record? 3. Does the hospital have a written policy on reporting deaths associated with seclusion or restraints to HCFA in a timely manner? 4. Do patient care staff know the HCFA death reporting requirements?

APPENDIX AA

PSYCHIATRIC HOSPITALS

INTERPRETIVE GUIDELINES

AND

SURVEY PROCEDURES

Appendix AA

Psychiatric Hospitals - Interpretive Guidelines and Survey Procedures

I. PRINCIPAL FOCUS OF SURVEYS

The principal focus of the survey is on the "outcome" of the hospital's implementation of requirements. Direct your principal attention to what actually happens to patients. The customer of the survey is the hospital, and/or the patient. What the hospital does is intended to reach the patient. Compliance is determined by the patients' need, and whether desired outcomes are achieved.

II. Task 1 - REPRESENTATIVE SAMPLE OF PATIENTS--SELECTION METHODOLOGY

A. Purpose of the Sample.--The purpose of drawing a sample of patients from the hospital is to reflect a proportionate representation from all certified program areas within the hospital. If the facility has a distinct part certified for participation in Medicare, care should be taken to assure that the patient sample is drawn only from program areas that participate in the distinct part certification.

While the patients in the sample are targeted for observation and interview, conduct each program audit of the patient within the context of the environments in which the patient lives, receives treatment and spends major leisure time. Although you may focus on the individual, the behavior and interactions of all other patients and staff within those environments also contribute to the total context and conditions for active treatment. Therefore, you may decide to include other patients in the overall sample.

The sampling process results in survey team judgements, rather than quantitative, criteria-based projections. It is not designed to be a "statistically valid" sample. Use flexibility when applying this method.

As the sample is built, additional information about the hospital's programs and services, as well as additional patient information may emerge. If you find a great disparity in numbers of patients in particular programs, adjust the sample to ensure that appropriate care and services are surveyed. Use your judgment in deciding the sample specifics within the parameters of the numerical requirements. Document your reasons for adding patients to the sample.

If you discover a significant group of patients with characteristics that has not been represented in the sample, add additional patients. Some examples are, finding several patients on specific Behavior Modification Programs; rapid tranquilization regimens; or discovering patients in seclusion and/or restraint during the course of the survey. You are free to add to the sample on a problem-oriented basis, or as dictated by individual needs. Substitute patients in the sample only if you find that it will be harmful and/or counter-therapeutic to include a specific patient. An example may be a patient with acute paranoid schizophrenia, who might become agitated if interviewed and observed.

B. SAMPLE SIZE.--Use the number of patients in the certified portion of the hospital rather than the number of beds in the certified portion of the hospital since those two figures may differ significantly. Calculate the size of the sample by using the following:

NUMBER OF PATIENTS IN HOSPITAL	NUMBER OF PATIENTS IN SAMPLE
Up to 100	8-10
101 - 250	10-12
251 - 400	13-15
401 - 500	16-18
Over 500	18-20

C. Sample Selection.--Do not allow the hospital to select the sample.

Draw a sample that distributes the patients among program areas of the hospital. Draw the sample randomly before beginning your tour of the hospital so that the base sample is not influenced by your observations. Request a listing of patients by program area, including admission date. Choose names randomly from that list, including, wherever possible, a representative number of newly admitted patients. If the hospital is unable to give you a list by program area, request a listing by unit and then determine the type of patients housed on each unit in order to reach a programmatic distribution. For instance, there may be more than one unit housing adult substance abuse patients. In that case, use the total number of those patients for sample distribution purposes. Another example would be a small hospital that houses patients with varying diagnoses and program needs on a single unit. An adult unit may house both substance abuse patients and eating disorder patients. In that case, divide those two groups for sample distribution purposes.

Attempt to draw a representative number of patients from each distinct program area based on the size of that program, unless the program areas are very disparate in size.

EXAMPLES:

1. A 120 bed hospital with four (4) program areas as follows:

Adult Admission	30 beds
Adolescent Admission	25 beds
Substance Abuse	35 beds
Chronic Care	30 beds

*CHOOSE 3 PATIENTS FROM EACH AREA

2. A 120 bed hospital with six (6) program areas as follows:

Children's Unit	10 beds
Adolescent Unit	20 beds
Adult Acute Care	20 beds
Substance Abuse	20 beds
Adult Intermediate Care	30 beds
Mentally Ill Offenders	20 beds

*CHOOSE 2 PATIENTS FROM EACH AREA

An even sample number will provide an adequate representation of all program areas. The child unit is smaller in bed number, but it is more important to adequately sample this specific treatment program than to produce a sample based solely on percentage of total beds.

3. Same as above, but the Adult Intermediate Care Unit has 10 beds, and the Children's Unit has 30 beds.

*This is an instance where your judgment is required. The following sample selections are appropriate depending on the factors considered by the survey team:

3 from the Children's Unit, 1 from the Adult Intermediate Care Unit, 2 from the other 4 units.

2 from each of the 6 units.

4. A 260 bed hospital with six (6) program areas as follows:

Mentally Ill Offenders 80 beds (4)

Eating Disorder Unit	20 beds	(2)
Adult Substance Abuse	40 beds	(2)
Adult Acute Unit	30 beds	(2)
Adolescent Acute Unit	40 beds	(2)
Geriatric Psychiatry	50 beds	(3)

*Suggested sampling is in parenthesis; however, surveyor judgment might result in an increase in the sample from the 20 bed Eating Disorder Unit (due to the variety of treatments found in such a program), by either decreasing the sample number on another unit or by adding an additional patient to the overall sample.

You are always free to add additional patients to the sample, if necessary. In the examples given, adjustments were made based on the unique treatment needs of certain groups of patients. Psychogeriatric patients or patients with substance abuse or eating disorders frequently have acute medical problems as well as acute psychiatric problems. Children who require psychiatric hospitalization are usually acutely ill, and have numerous treatment needs. If you are not comfortable adjusting the sample to accommodate these program areas, increase the sample size of patients from these special treatment programs. The result will be an overall increase of the total number of patients in your sample. Document the reasons for adjusting the sample, and retain in the official survey file.

D. Program Audit Approach.--To maximize the advantage of an interdisciplinary survey, team members each assume an equitable number of patients from the various program areas on which to focus. For each patient, assess all applicable areas of the Two Special Conditions of Participation for Psychiatric Hospitals. You are to consult with one another, on a regular basis during the survey, to maximize sharing of knowledge and competencies.

III. TASK 2 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

A. Introduction.--Review each patient's record in your sample for compliance with the Special Medical Record Condition's Standards (refer to the specific interpretive guidelines and survey procedures under Special Medical Record Condition). You should be aware that hospitals are increasingly using integrated data bases, particularly in the areas of evaluations and treatment plans. Separate data collection is not a problem as long as it is integrated into multidisciplinary evaluations and treatment plans. Do not spend an excessive amount of time looking at fine details in the record review of the selected sample. The primary purpose is to determine what the hospital has committed itself to do for the patient under that patient's treatment plan, whether the treatment plan is being implemented, and whether patients are experiencing the outcomes desired from the treatment plan. The record review portion of the optional Patient Sampling Form (HCFA Form-725) is one place to record pertinent information.

B. Other pertinent information.--Early in the survey, review accident and incident profiles for any evidence that suggests that patients are being abused, abusing each other, or are vulnerable to abuse and injury. If you recognize patterns that suggest abuse, follow-up on the status and condition of those patients if they are still hospitalized. Review seclusion and restraint records for any evidence that suggests these procedures are being overused and/or used for non-therapeutic reasons. Review medication error profiles for evidence that suggests jeopardy to patients. All team members should participate in reviewing pertinent information.

IV. TASK 3 - OTHER RECORD REVIEWS

A. Death Records.--Review a list of all of the deaths of patients since the last survey, and review in detail the medical records of all patients who died as a result of suicide, homicide, and other unexpected conditions. All team members participate in the record review of patients who have died.

If there is a physician on the survey team, consult with him/her regarding problems found. In those hospitals participating as a Distinct Part, review only those records of patients from the Distinct Part who died. For additional guidance, refer to the optional Form HCFA 726, HCFA Death Record Review Data Sheet.

B. Discharge Records.--All survey team members are responsible for reviewing discharge records for compliance with the Discharge Planning Standard (see specific instructions under that Standard's interpretive guidelines and survey procedures). Review only the discharge summaries and discharge plans. The survey team reviews no less than five (5), but no more than ten (10), discharge records. The records will represent several or all program areas. Do not allow the hospital to select the records.

C. Complaint Investigations.--If a complaint is being investigated at the time of the survey, include the medical record(s) of the subject(s) of the complaint as part of the record review. If the patient named in the complaint is still in the hospital, add him/her to your sample.

V. TASK 4 - DIRECT PATIENT OBSERVATIONS

A. Purpose.--Determine if the necessary relationship between what the treatment plan says, what the staff know and do with patients, in both formal and informal settings throughout the day and evening, and what outcomes patients experience, is actually made. Observe each sampled patient (after obtaining the patient's permission) in as many treatment modalities (groups, activities, treatment team meetings, other types of meetings, and milieu interactions in the patient's environment) as possible. Visit as many of these modalities as you can. Conduct observations over as much of the day and evening timespan as possible; team members may choose to alter their work schedules so that observations can be made during most of the patients' waking hours. It is not appropriate to ask the facility to alter a patient's schedule so that you will not have to work at other than your regular work times in order to see the patient during the survey. Conduct a minimum of two (2) separate observations (you may do more) of each patient in your sample, including at least one observation in an informal setting during non-structured time.

B. Documentation.--Record all of your observations. For additional guidance, refer to the Form HCFA-725. If your behavior or presence disrupts the modality being observed, wait until the modality has ended to record your observations.

Record the following information for each observation:

- Date and location;
- Beginning and ending times of observation;
- Number of patients present;
- Approximate number of staff/volunteers present;
- Identify the modality in progress;
- What the patient is doing (regardless of whether or not a scheduled treatment modality was in progress);
- What the patient is actually scheduled to be doing during the time interval of the observation;
- If the modality or intervention is related to the specific Treatment Plan goals and objectives;

o Patient's level of participation in the activity;

o Presence of disruptive behavior, and staff's intervention, if any;

o Surveyor's assessment as to whether the treatment plan was carried out, the patient's needs were met, the observed interaction/activity was individualized to meet the patient's needs, and whether active treatment was provided; and

o Any other pertinent information

You should observe the modality for an amount of time sufficient to assess your sampled patient's responses.

VI. TASK 5 INTERVIEWS

A. Patient Interviews.--Interviews with patients consist of questions directed at determining the patient's understanding of his or her treatment plan. Interviewing a patient takes place after asking staff if the interview will not disturb that patient. When an interview is inappropriate the survey for that patient will consist of observations. Interviewing may take place in the presence of staff. For further guidance on conducting these interviews, please refer to the instructions on the Form HCFA-725. Patient confidentiality must be respected, but if the surveyor does find a life-threatening situation, that information is shared with the staff.

B. Purpose of Structured Interviews Related to Patient Staffing.--Interviews are required as part of the patient sampling and program audit approach. Conduct these interviews to secure information about effects of treatment only to the extent that further information necessary to make compliance decisions is not available through individual observations. Use the following hierarchy of "sources", to the maximum extent possible, in the order shown:

o Patient (unless unwilling or unable to be interviewed);

o Assigned responsible staff member (case manager, primary therapist, patient care coordinator; and

o Other staff members who are involved with the patient, either through multidisciplinary treatment assignment (social worker, dance therapist, dietician) or through work assignment (professional and paraprofessional staff members assigned to patient's unit).

During the interviews, ask questions that elicit information about how the staff integrate treatment plan goals and objectives with treatment approaches and interventions. Look for consistent treatment approaches among disciplines as well as the outcomes experienced by the patients.

C. Documentation.--Record each interview you conduct with patients and staff. Include the following information in your notes for each:

o Position, title and assignment of staff member;

o Relationship to the patient or reason for interview; and

o Summary of information obtained.

D. Interviews with Major Department Directors.--See the specific Interpretive Guidelines and Survey Procedures for The Special Staffing Condition for the content of departmental staff interviews. Conduct those

interviews toward the end of the survey so that you will have sufficient data from observations and direct interviews with patients and staff to ask pertinent questions of the departmental director. Do not spend an excessive amount of time interviewing departmental directors. Give all of the staffing data forms (Form HCFA-727, Form HCFA-728 and Form HCFA-729) to the department heads at the beginning of the survey so that enough time is allowed to compile the necessary information for your review prior to the formal interview.

VII. TASK 6 - VISIT TO EACH AREA OF THE HOSPITAL SERVING CERTIFIED PATIENTS

A. Purpose.--By the end of the survey, visit each place where certified patients receive treatment in order to insure that the hospital is providing services in the manner required by the regulations. Examples of such areas are: cafeteria, gymnasium, and classroom. It is not necessary to visit those hospital departments that are "deemed" or surveyed under the General Hospital Conditions; such as Pharmacy, and Dietary Department.

B. Protocol.--After patients in the sample have been assigned to team members, review the facility's map or building layout. Be sure that at least one team member visits each residential and treatment site prior to completing the survey. Record your observations in your notes. The visit or tour can be conducted at any time during the course of the survey.

During the visit or tour converse with patients and staff. Ask open-ended questions in order to confirm observations, obtain additional information, or corroborate information regarding perceived problems. Observe staff interactions with both patients and other staff members for insight into matters such as individual rights and staff responsibilities.

Always get permission before entering a room. If it is necessary to observe a treatment procedure, or to observe a patient who is exposed, courteously ask permission from the patient if she/he comprehends, or from the staff if the individual cannot communicate. If patient physical contact is required to note a treatment or visually examine a bruise, a staff person, not the surveyor, should touch the patient.

VIII. TASK 7 - TEAM ASSESSMENT OF COMPLIANCE

A. Pre-exit Meeting.-- At this meeting, the surveyors will share their respective findings, and make team decisions regarding compliance with each standard and condition of participation. All necessary forms (HCFA-2567, HCFA-670, HCFA-1513, HCFA-1514, and HCFA-724) should be completed. The team leader completes any additional optional forms (HCFA-725, HCFA-726, HCFA-727, HCFA-728, and HCFA-729) that may be needed for the official file.

B. Role of the Team Leader.-- At the beginning of the survey, determine who will be the survey team leader. This task may be assigned or rotated. The team leader ascertains that all survey team members have completed their respective survey tasks prior to the surveyor pre-exit meeting. It is the team leader's responsibility to assure that the following documentation has been completed for the official file:

1. Summary listing of all patient information comprising the survey sample (including any additions to the sample). At a minimum, identify:

   - The medical record number of each patient chosen to be part of the sample;

   - Any patient-identifier codes used as a reference to protect the patient's confidentiality; and

- The medical record number of each discharge and death record reviewed.

2. Description of the representative sample selection. At a minimum, identify, at the time of the survey:

   - The number of patients in the sample;
   - The distribution of the individuals in the sample across the hospital's program areas; and
   - The number, if any, of the patients added to the sample, and the reason.

C. General.--Transfer to the HCFA-2567 all examples of evidence obtained from your observations, interviews, and record reviews. Transfer those findings that contribute to a determination that the facility is deficient in a certain area.

D. Special Circumstances.--If at any time during the survey one or more team members identify(ies) a possible immediate and serious threat, the team should meet immediately to confer. See Appendix Q for the definition of immediate and serious threat, and for guidance regarding determination of immediate and serious threat.

IX. COMPLETING FORMS HCFA-724 THROUGH HCFA-729 FOR PSYCHIATRIC HOSPITAL OUTCOME ORIENTED SURVEY

HCFA-724 MEDICARE/MEDICAID PSYCHIATRIC HOSPITAL SURVEY DATA

General Instructions

This is the cover sheet for the psychiatric hospital survey of the two special conditions. This form summarizes data relative to: hospital characteristics; types of services provided by the hospital; and hospital statistics.

Specific Instructions

Section I

Instruct hospital staff to complete this section of the form.

1. Complete all portions.
2. Blocks 1 through 6, enter identifying data, as requested.
3. Block 7 - Total number of beds, refers to the total bed capacity of the hospital.
4. Block 8 - Total number of certified beds refers to the current number of Medicare Certified Beds.
5. Block 9 - Enter identifying data as requested.
6. Block 10 - (A,B,C) Hospital may choose to give this data for either the last calendar or fiscal year.
7. Item 13. Current statistics refers to the statistical data relative to the certified beds on the day of the survey.

Section II TO BE COMPLETED BY THE SURVEY TEAM

1. Complete all portions.

2. Block 16 - check all that apply.

3. Block 17 - Check all disciplines represented.

4. Block 18 - check all that apply, and at B36 enter the total number of surveyors on site.

5. Block 19 - must be signed by each surveyor.

HCFA-725 SURVEYOR WORKSHEET FOR PSYCHIATRIC HOSPITAL REVIEW: TWO SPECIAL CONDITIONS (Optional)

General Instructions: Use of this form is optional, but the surveyor must collect all the information even if he/she chooses not to use this specific form.

Specific Instructions:

SECTION I

Enter identifying data as requested.

SECTION II Document the relevant information for both structured (specific treatment modalities) and unstructured (milieu) observations. The documentation will include the specific items listed in the first column, and any additional items that the surveyor considers pertinent. Use additional sheets, if necessary.

SECTION III Include those relevant items from the patient's current treatment plan which will enable the surveyor to determine whether or not active, individualized treatment is being provided.

(Col. 1) Enter the Problem(s).

(Col. 2) Enter the corresponding long and short term goals with projected outcome dates.

(Col. 3) Enter the corresponding intervention specifics for that problem. Document what will be done, who will do it (name and discipline), as well as any statements as to the expected outcome of the interventions.

(Col. 4) Use this column to note concerns or issues for further investigation.

SECTION IV Document with a "y" or "n" whether each Medical Record item is in compliance (present in the medical record).

SECTION V Document information obtained from the patient interview, including, at a minimum, the areas indicated in the sample questions box at the left margin.

SECTION VI Document information obtained from the staff interview, including, at a minimum, the areas indicated in the sample questions box at the left margin.

SECTION VII The surveyor should use this space to document any additional data, either from the previous sections, or any other pertinent information.

HCFA-726 HCFA DEATH RECORD REVIEW DATA SHEET (Optional)

General Instructions

This is the information gathered from the review of all suicides, homicides and unexpected deaths. Use of this form is optional, but the surveyor must collect all the information even if he/she chooses not to use this specific form.

Specific Instructions

SECTION I

Enter identifying data as requested. The physical diagnosis may be listed as Axis III diagnosis, since that is the form most often used in psychiatric records.

SECTION II

Complete all three portions. For all abbreviations used, write the complete name the first time used. In concluding whether proper treatment was provided, review and document the treatment provided prior to death, and the final events leading to death.

HCFA-727 HCFA NURSING COMPLEMENT DATA (Optional)

General instructions

1. This is the data sheet for the collection of direct care nursing personnel for certified units for a 24 hour period during the time of the survey. This data is collected for at least 25% of the certified units; each unit requires a separate form. The surveyor may decide to gather data on additional units and/or for additional days. Use of this form is optional, but the surveyor must collect all the information even if he/she chooses not to use this specific form.

2. Complete all portions of the form.

3. If a number is requested and the answer is "none" or "zero", enter a "0" in the space provided.

4. Abbreviations used:

FTE	Full-Time Equivalent
RN	Registered Nurse
LPN	Licensed Practical/Vocational Nurse
MHW/Tech.	Mental Health Worker/Psychiatric Technician. All paraprofessional health care workers who report to nursing service.
Clinical Spec.	Masters prepared Registered Nurses
Non-NSG Personnel	security/escort services, and certified addiction counselors.

Specific Instructions

1. Enter identifying data as requested.

2. Patient type means a brief description of the patient characteristic of the unit (e.g., eating disorders, psycho-geriatric, acute admissions).

3. The specific instructions for the Staffing Matrix are as follows: Enter the number of FTE's of the direct care nursing personnel in each listed category. Do not include nursing supervisors, clinical nurse specialists, educators, etc., unless these personnel are assigned to that unit to provide direct care. Do not include staff who are in training programs, orientation class, etc. The surveyor should suggest that this data can most accurately be provided by each unit's nurse manager.

4. Enter the total number of clinical specialists who are available to provide guidance and consultation to unit staff, but do not include any clinical specialists who are assigned as RN unit staff.

5. The nurse surveyor and the Director of Nursing should sign the form, thereby attesting to its accuracy.

HCFA-728 HCFA TOTAL NURSING STAFF DATA (Optional)

General Instructions

1. This is the data sheet for the collection of direct care nursing personnel numbers for the TOTAL certified beds in the facility at the time of the survey. Use of this form is optional, but the surveyor must collect all the information even if he/she chooses not to use this specific form.

2. If a number is requested and the answer is "none" or "0", enter a "0" in the space provided.

3. Abbreviations are the same as those listed under the General Instructions for the HCFA-727.

Specific Instructions

1. Enter the identifying data as requested.

2. The specific instructions for the Matrix are: enter the number of FTE's of the direct care nursing personnel in each listed category. Do not include nursing supervisors, clinical specialists and educators, whose summary function is other than the provision of direct patient care. Do not include personnel who are on extended leaves of absence, such as convalescent leave for more than one month, or leave to pursue a college degree. Float pool and/or agency personnel should not be included in the matrix, but, if such persons are utilized on a regular basis, that fact should be noted separately.

3. Both the nurse surveyor and the Director of Nursing should sign the form, thereby attesting to its accuracy.

HCFA-729 DATA COLLECTION MEDICAL STAFF COVERAGE (Optional)

General Instructions

This is the data collection form for TOTAL medical staff coverage (all specialties). Use of this form is optional, but the surveyor must collect all the information even if he/she chooses not to use this specific form.

Specific Instructions

1. Enter the identifying data as requested.
2. In part 1 of the matrix, list all those medical staff who are employees of the hospital.
3. In part 2 of the matrix, list all those medical staff who are consultants to the hospital.
4. The medical director or supervisor of residents (if there is such a position) is the appropriate source of the information for block 3.
5. On-Call medical coverage in block 4, means physician availability during other than normal business hours.
6. Enter the number of FTE vacancies in block 5.
7. Enter the number of FTE's on any leave of absence that is greater than one month.
8. Both the surveyor and the Clinical Director should sign the form, thereby attesting to its accuracy.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B98	§482.60 Conditions of Participation:Special provisions applying to psychiatric hospitals. Psychiatric hospitals must--	
B99	(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.	§482.60(a) GUIDANCE: The hospital will be deemed to meet standard (a) if it meets standards (c) and (d).
B100	(b) Meet the Conditions of Participation specified in"482.1 through 482.23 and "482.25 through 482.57;	§482.60(b) GUIDANCE: The hospital is either accredited by JCAHO or AOA; or meets the Condition of Participation for Hospitals, "482.1 through 482.23 and "482.25 through 482.57.
B101	(c) Maintain clinical records on all patients, including records sufficient to permit HCFA to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in '482.61; and	

B102	(d) Meet the staffing requirements specified in '482.62.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B103	§482.61 Condition of Participation: Special medical record requirements for psychiatric hospitals The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.	§482.61 GUIDANCE: The clinical record should provides information that indicates need for admission and treatment, treatment goals, changes in status of treatment and discharge planning, and follow-up and the outcomes experienced by patients. The structure and content of the individual patient's record must be an accurate functional representation of the actual experience of the individual in the facility. It must contain enough information to indicate that the facility knows the status of the patient, has adequate plans to intervene, and provides sufficient evidence of the effects of the intervention, and how their interventions served as a function of the outcomes experienced. You must be able to identify this through interviews with staff, and when possible with individuals being served, as well as through observations.
	(a) Standard: Development of assessment/diagnostic data.	
B104	Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.	
B105	(1) The identification data must include the patient's legal status.	§482.61(a)(1) GUIDANCE: Definition: Legal Status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated - i.e., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements. Determine through interview with hospital staff the terminology they use in defining "legal status." If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Changes in legal status should also be recorded with the date of change.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B106	(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis.	§482.61(a)(2) GUIDANCE: There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. This diagnosis is made and entered into the chart of each patient at the time of the admission examination. The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change. If a diagnosis is absent, there must be justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others. Intercurrent (other than psychiatric) diagnoses must be documented when they are made. Attention should be paid to physical examination notes, including known medical conditions, even allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis. These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the "admission work up " or the physician's progress notes. Diagnostic categories should include physical illness when present. '§82.61 (a) (2) PROBES Are abnormal physical examination findings and/or laboratory findings justified by further diagnostic testing and/or development of an intercurrent diagnosis, and, if so, was such done? If an identified physical illness requires immediate treatment, is the treatment being given? How will an identified physical illness be likely to impact on the patient's eventual outcome? To what extent has this potential impact been addressed by the team?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B107	(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.	§482.61(a)(3) GUIDANCE: The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient's response to admission. The hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers. Records should not contain vague, ill-defined reports from unknown sources. Records should record "who", "what", "where", "when", and "why." §482.61 (a) (3) PROBES: Can the patient describe problems, stresses, situations experienced prior to hospitalization or do they still exist? Who is the informant? Did the informant witness the patient's behavior? If not, on what basis has the informant come to know the patient's behavior? Has staff elicited whether the patient has exhibited similar behavior previously? If so, what was different this time to make hospitalization necessary? Were there other changes/events in the patient's environment (death, separations of significant others) which contributed to the need for hospitalization? If so, has staff explored how these will impact in the patient's treatment? Has this been addressed by the treatment team? Has there been an interruption or change in the patient's medication which may have been a factor in the patient's hospitalization?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B108	(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.	4) GUIDANCE: The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated. Patient length of stay is a key factor influencing hospital documentation policy, i.e., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record. A psychosocial history/assessment must be completed on all patients. Three key components to be addressed: A. Factual and Historical Information 1. Specific reasons for the patient's admission or readmission; 2. A description of the patient's past and present biopsychosocial functioning; 3. Family and marital history, dynamics, and patient's relationships with family and significant others; 4. Pertinent religious and cultural factors; 5. History of physical, sexual and emotional abuse; 6. Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others; 7. Educational, vocational, employment, and military service history; 8. Identification of community resources including previously used treatment sources; 9. Identification of present environmental and financial needs. B. Social Evaluation 1. Patient strength and deficits; 2. High risk psychosocial issues requiring early treatment planning and intervention - ie, unattended child(ren) in home; prior noncompliance to specific treatment and/ or discharge interventions; and potential obstacles to present treatment and discharge planning. C. Conclusions and Recommendations Assessment of Sections A and B shall result in the development of (C) recommendations related to the following areas: 1. Anticipated necessary steps for discharge to occur; 2. High risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay; 3. Specific community resources/ support systems for utilization in discharge planning - i.e., housing, living arrangements, financial aid, and aftercare treatment sources; 4. Anticipated social work role(s) in treatment and discharge planning.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§482.61 (a) (4) PROBES Does the psychosocial history/assessment indicate: 1. Clear identification of the informants(s) and sources of information? 2. Whether information is considered reliable? 3. Patient participation to the extent possible in provision of data relative to treatment and discharge planning? 4. Integration of significant data including identified high risk psychosocial issues (problems) into the treatment plan? How does the hospital insure the information is reliable?
B109	(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.	§482.61(a)(5) GUIDANCE: Upon admission the patient should receive a thorough history and physical examination with all indicated laboratory examinations. These investigations must be sufficient to discover all structural, functional, systemic and metabolic disorders. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness. Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder. The screening neurologic examination As part of the physical examination, the physician will perform a "screening" neurologic examination. While there is no precise definition of a screening neurologic examination in medical practice such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detailed, fine testing of each division. Gross testing of Cranial Nerves II through XII should be included. Statements such as "Cranial Nerves II to XII intact" are not acceptable. These areas may be found in various parts of the physical examination and not just grouped specifically under the neurologic. In any case where a system review indicate positive neurologic symptomatology, a more detailed examination would be necessary, with neurologic work-up or consultation ordered as appropriate after the screening neurologic examination was completed.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Complete neurologic examination. A complete, comprehensive neurologic examination includes a review of the patient's history, physical examination and for psychiatric patients, a review of the psychiatric evaluation. The neurologist/psychiatrist himself/herself also takes a history to obtain the necessary information not already available in the medical record or referral form. The neurologic examination is a detailed, orderly survey of the various sections of the nervous system. As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient's sight (cranial nerve II) in a complete neurologic examination, the neurologist may test visual acuity with a snellen chart, perform a fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient's visual fields. In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even individual muscles are tested. In a complete neurologic examinations all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested. §482.61(a)(5) PROBES: Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of an intercurrent diagnosis? If the finding justified further follow-up in either situation, was such follow-up done? Is there evidence that a screening neurologic examination was done and recorded at the time of the physical examination? Was the screening neurologic or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma? If indicated, was a complete, comprehensive neurologic exam ordered, completed and recorded in the medical record in a timely manner?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(b)Standard: Psychiatric evaluation	
B110	Each patient must receive a psychiatric evaluation that must-	§482.61(b) GUIDANCE: The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment. The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness. Through the psychiatric evaluation the physician seeks to secure a biographical-historical perspective of the patient's personality, with a clear psychological picture of the patient as a specific human being with his or her individual problems. While performing the psychiatric evaluation, the physician reaches an understanding of the patient's basic personality structure, of the patient's developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness. In the psychiatric evaluation the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity. The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment. A physician's signature is necessary. In those cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is credentialed by the hospital, legally authorized by the State to perform that function, and a physician review and countersignature is present, where required by hospital policy or State law. In order to satisfy the requirements '482.61 (b) (1-7) of this standard, and to meet the standards of medical practice, the psychiatric evaluation should include the following component parts:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§482.61(b) PROBES: 1- The patient's chief complaints and/or reaction to hospitalization, recorded in patient's own words where possible. Why is the patient in the hospital? Was it his/her idea? (Does he/she feel ill/disturbed/frightened?) Is the patient in the hospital against his/her will? Who decided to hospitalize/why? 2- Past history of any psychiatric problems and treatment, including prior precipitating factors, diagnosis, course and treatment. Has the patient been chronically ill? Continuously/repeatedly? How severely has the past illness/treatment interfered with the patient's development and/or adjustment? Are there persistent symptoms/signs/behaviors which must be addressed and treated in order to favorably impact on the future psychiatric course? What medications or supports helped him/her improve in the past? Are the same resources available to impact on the patient's treatment during this episode? 3- Past family, educational, vocational, occupational and social history. To what extent, if any, is there a presence or absence of familial predisposition? What is the patient's educational level? Was he/she a good student? Is he/she still interested in learning? What jobs has the patient held? For how long? Is he/she now employed/unemployed? For how long? Has he/she ever worked? How does the patient get along with people? As a child, did he/she have friends? Does he/she have friends now? 4- Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors, that justify the diagnosis?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B111	(1) Be completed within 60 hours of admission;	
B112	(2) Include a medical history;	§482.61(b)(2) GUIDANCE: The psychiatric evaluation must include the non-psychiatric medical history including physical disabilities, mental retardation and treatment. §482.61(b)(2) PROBES: Does the evaluation include: Relevant past surgery? Past medical conditions and disabilities especially those of a chronic nature? Have these contributed to the patient's psychiatric condition? How? Are any of these conditions still present to any significant degree? Are they likely to impact on the patient's recovery/remission? Should they be addressed immediately? Does the facility have the capability to intervene? If not, how is the need to be met?
B113	(3) Contain a record of mental status;	§482.61(b)(3) GUIDANCE: The mental status must describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination. This description is appropriate to the patient's condition. Explore the mental status for descriptions of the patient's presentation during the examination that are relevant to the diagnosis and treatment of the patient. An example of a portion of the patient interview: The patient periodically states the examiner's name correctly during this examination after hearing it once, accurately describes his past history in great detail, precisely characterizes his present situation, can list events in logical sequence that have led to his present illness, but believes that his pre-admission insomnia, anorexia, and 35 pound weight loss over the past four months are totally the result of his sexual promiscuity of ten years ago and have nothing to do with his concurrent use of 50 to 60 mg. of Amphetamine daily." From this information one can conclude that the patient is oriented, his memory is intact, but that he has poor judgment and no insight. It is not acceptable just to write "oriented, memory intact, judgement poor, and insight nil", without any supportive information.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B114	(4) Note the onset of illness and the circumstances leading to admission;	§482.61(b)(4) GUIDANCE: In a hospitalized patient, the identified problem should be related to the patient's need for hospital admission. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received. §482.61(b)(4) PROBES: How long has the patient been ill? Was it a gradual or sudden onset? Is this a recurrence? What were the precipitating factors? What happened? What symptoms, signs, behaviors made this hospitalization necessary? What treatment has the patient already received before coming to the hospital? Is any medication he received listed?
B115	(5) Describe attitudes and behavior;	§482.61(b)(5) GUIDANCE: The problem statement should describe behavior(s) which require change in order for the patient to function in a less restrictive setting. The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.
B116	(6) Estimate intellectual functioning, memory functioning and orientation;	§482.61(b)(6) GUIDANCE: Refer to '482.61(b)(3)
	and	
B117	(7) Include an inventory of the patient's assets in descriptive, not interpretive fashion.	§482.61(b)(7) GUIDANCE: Although the term strength is often used interchangeably with assets, only the assets which describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan. For purposes of the regulation, words such as "youth," "pretty," "Social Security income," and "has a car" do not represent assets. (See also §482.61(c)(1).)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(c)Standard: Treatment Plan.	
B118	Each patient must have an individual comprehensive treatment plan	§482.61 (c)(1) GUIDANCE: The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan is the outline of what the hospital has committed itself to do for the patient, based on an assessment of the patient's needs. The facility selects its format for treatment plans and treatment plan updates. §482.61(c)(1) SURVEY PROCEDURE: Determination of compliance regarding treatment plans is accomplished by the surveyor using the following methods, and to the extent possible, the following order: (1) Observation of the patient and staff at planned therapies/meetings, in various settings both on and off the patient units, in formal and informal staff-patient interactions and in a variety of daily settings; (2) Interviews with patients, families, treatment staff and others involved directly or indirectly with active treatment; (3) Reviews of scheduled treatment programs (individual, group, family meetings, therapeutic activities, therapeutic procedures); (4) Attendance at multidisciplinary treatment planning meetings, if time permits; and (5) Medical record review. §482.61(c)(1) PROBE: Has the information gained from assessing/evaluating the patient been utilized to create an individualized treatment plan?
B119	The plan must be based on an inventory of the patient's strengths and disabilities.	§482.61(c)(1) GUIDANCE: A disability is any psychiatric, biopsychosocial problem requiring treatment/intervention. The term disability and problem are used interchangeably. The treatment plan is derived from the information contained in the psychiatric evaluation and in the assessments/diagnostic data collected by the total treatment team. Based on the assessment summaries formulated by team members of various disciplines, the treatment team identifies which patient disabilities will be treated during hospitalization. Patient strengths which can be utilized in treatment must be identified. (See also '482.61(b)(7).) Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the hospital stay, the fewer disciplines may be involved in the patient's treatment.

	REGULATION	GUIDANCE TO SURVEYORS
		There must be evidence of periodic review of the patient's response and progress toward meeting planned goals. If the patient has made progress toward meeting goals, or if there is a lack of progress, the review must justify: (1) continuing with the current goals and approaches; or (2) revising the treatment plan to increase the possibility of a successful treatment outcome. Consideration must be given to the type of psychiatric program(s) under review to determine the timeframe for treatment plan review. The interval within which treatment plan reviews are conducted is determined by the hospital, however, the hospital's review system must be sufficiently responsive to ensure the treatment plan is reviewed: whenever a goal(s) has been accomplished; when a patient is regressing; when a patient is failing to progress; or when a patient requires a new treatment goal. The facility is expected to pursue aggressively the attendance of all relevant participants at the team meetings. Question any routine and regular absences of individuals who would be expected to attend. §482.61(c)(1) PROBES: Is the treatment plan individualized, i.e., patient-specific, or is there a predictable sameness from plan to plan? When packaged plans or programs are used, do staff include needed individual adaptations in the plan? Are the patient's observed behaviors consistent with the problems and strengths identified in the plan or update? Have the views which the patient communicated to the surveyor regarding problems which require treatment during hospitalization and plans for discharge, been incorporated in the plan or update?
	The written plan must include--	
B120	(i) A substantiated diagnosis;	§482.61(c)(1)(i) GUIDANCE: The substantiated diagnosis serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.

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		At the time of admission, the patient may have been given an initial diagnosis or a rule-out diagnosis. At the time of treatment planning, a substantiated diagnosis must be recorded. It may be the same as the initial diagnosis, or, based on new information and assessment, it may differ. Rule-out diagnoses, by themselves are not acceptable as a substantiated diagnosis. Data to substantiate the diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others. §482.61 (c) (1) (i) PROBES What specific problems will be treated during the patient's hospitalization? Does the treatment plan identify and precisely describe problem behaviors rather than generalized statements i.e., "paranoid," "aggressive," "depressed?" or generic terminology i.e., "alteration in thought process," "ineffective coping," "alteration in mood?" Are physical problems identified and included in the treatment plan if they require treatment, or interfere with treatment, during the patient's hospitalization?
B121	(ii) Short-term and long range goals;	§482.61(c)(1)(ii) GUIDANCE: Based on the problems identified for treatment, short-term and long range goals are developed. Whether the use of short-term or a combination of short-term and long range goals is appropriate is dependent on the length of hospital stay. Short-term and long range goals include specific dates for expected achievement. As goals are achieved, the treatment plan should be revised. When a goal is modified, changed or discontinued without achievement, the plan should be reviewed for relevancy, and updated as needed. In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of hospital stay increases (often because of the long-term chronic nature of the patient's illness), both long range and short-term goals are needed.

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		The long range goal is achieved through the development of a series of short-term goals, i.e., smaller, logical sequential steps which will result in reaching the long range goal. Both the short-term and long range goals must be stated as expected behavioral outcomes for the patient. Goals must be related to the problems identified for treatment. Goals must be written as observable, measurable patient behaviors to be achieved. Discharge criteria may be included as long range goals. '482.61(c)(1)(ii) PROBES: How do treatment plan goals relate to the problems being treated? Do goals indicate the outcomes to be achieved by the patient? Are the goals written in a way that allow changes in the patient's behavior to be measured? If not apparent, what criteria do staff use to measure success? How relevant are the treatment plan goals to the patient's condition?
B122	(iii)The specific treatment modalities utilized;	§482.61(c)(1)(iii) GUIDANCE: This requirement refers to all of the planned treatment modalities used to treat the patient during hospitalization. Having identified the problems requiring treatment, and defining outcome goals to be achieved, appropriate treatment approaches must be identified. Modalities include all of the active treatment measures provided to the patient. It describes the treatment which will be provided to the patient. It describes the treatment which will be provided by various staff. A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient attends various treatment modalities/activities, it is a part of individualized planning with a specific purpose and focus for that patient. Simply "naming" modalities (i.e., individual therapy, group therapy, occupational therapy, medication education) is not acceptable. The focus of the treatment must be included. Simply "stating" modality approaches (i.e., "set limits," "encourage socialization," "discharge planning as needed") is not acceptable. Modality approaches must be specifically described in order to assure consistency of approach.

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		Observation of staff implementing treatment, both in structured and non-structured settings, is a major criterion to determine whether active treatment is being provided in accordance with planned treatment. It must be clear to you that the active treatment received by the patient is internally consistent and not simply a series of disconnected specific modalities delivered within certain scheduled intervals. §482.61(c)(1)(iii) PROBES: Are qualified staff observed following the methods, approaches and staff intervention as stated? Can staff explain the focus of the modality they have provided? Are observed treatment methods, approaches and interventions from all disciplines included in the plan? Do the pieces of the treatment plan work together to achieve the greatest possible gain for the patient? Does the hospital integrate its activities, therapies, treatments, and patient routines to work for the patient's therapeutic interests first, and its own convenience second? Do the disciplines present at observed treatment planning meetings represent all of the patient's needs? If the patient attends treatment planning, how do the staff prepare the patient to participate? If the patient does not attend, what reasons do staff give to explain the absence? Is there a process to enable staff to reach a consensus regarding how treatment will be carried out? Is the patient included in the decision-making, whenever possible? Are the final decisions regarding treatment approaches defined clearly by the end of the discussion? How does the patient get to know his/her treatment regime? How does the treatment team encourage the patient to accept responsibility for engaging in the treatment regime, rather than accepting it passively?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B123	(iv) The responsibilities of each member of the treatment team;	§482.61(c)(1)(iv) GUIDANCE: There are no "correct" number of staff who comprise the treatment team. The disciplines involved in the patient's treatment depend upon the problems to be treated, the short-term and long range goals and the treatment approaches and modalities used to achieve the goals. The intent of the regulation is to insure that each individual on the treatment team who is primarily responsible for ensuring compliance with particular aspects of the patient's individualized treatment program is identified. Identification of the staff should be recorded in a manner that includes the name and discipline of the individual. If other professionals or paraprofessionals provide care, the facility has the latitude to decide the manner with which it will identify them on the treatment plan. The patient, as well as family/significant others, should be aware of the staff responsible for various aspects of treatment. §482.61(c)(1)(iv) PROBES: Are staff who are designated in the treatment plan observed carrying out treatment activities and therapies? Is the information in the plan consistent with surveyor observations? Are the patients able to name the staff responsible for implementing their treatment? Is this information consistent with the treatment plan?
	and	
B124	(v)Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.	§482.61(c)(1)(v) GUIDANCE: When the progress and treatment notes are reviewed, the content of the notes must relate to the treatment plan. The notes must indicate what the hospital staff is doing to carry out the treatment plan and the patient's response to the interventions. §482.61(c)(1)(v) PROBES: Are the treatment notes relative to the identified problems? Are the treatment notes indicative of the patient's response to treatment? Do the progress notes relate to specific patient problems or progress?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B125	(2)The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.	§482.61(c)(2) GUIDANCE: Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist. The patient is in the hospital because it has been determined that the patient requires intensive, 24 hour, specialized psychiatric intervention that cannot be provided outside the psychiatric hospital. The medical record must indicate that the hospital adheres to the patient's right to be counseled about medication, its intended effects, and the potential side-effects. If the patient requires, because of danger to self or others, a more restrictive environment, the hospital must indicate that the staff attempted to care for the patient in the least restrictive setting before progressing to a more restrictive setting. Through observation, look for evidence that each patient is receiving all the aspects of treatment to which the hospital has committed itself based upon his/her assessment, evaluation and plan of care. It is the hospital's responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning. Through observation and interviews, look for evidence that each patient's rights are being addressed and protected. There should be policies and procedures in place to address the following areas: informed consent, confidentiality, privacy, and security. Expect to see detailed policies and procedures regarding the therapeutic use of restrictions, such as visitors, mail, and phone calls. Seclusion and restraint policies and procedures must address patient protection and safety while in a restricted setting. Clarification of the types of notes found in the medical record. **Treatment notes** are recordings in the medical record that indicate provision of, and a patient's response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician or anyone credentialed by the facility, in accordance with the State law, to write orders in the medical record. A combined treatment and progress note may be written. **Progress notes** are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan. These are frequently shift notes, weekly notes, or monthly notes.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§482.61(c)(2) PROBES: Does the patient know his/her diagnosis? What did the patient contribute to the formulation of the treatment plan? Goals of treatment? If the patient receives medication, does the patient understand the reason for the medication? The name of the medication? The dose prescribed? The time of administration? The desired effects? The potential side-effects? If medication is changed, is there a rationale for the change? Are staff members recording their observations relative to the patient's response to the treatment modalities, including medication? Is there evidence that the patient was afforded the opportunity to participate in his/her plan of care? What progress has the patient made? Has the patient achieved his/her optimal level of functioning? If not, why? Are these reasons/barriers reflected in the current treatment plan? Do treatment and progress notes support these insights? Does the observed status of the patient in the various treatment modalities correspond to the progress note reports of status? Do all treatment team members document their observations and interventions so that the information is available to the entire team? If a restrictive procedure is used (e.g., restraint and/or seclusion), is there evidence that attempts were made systematically to treat the patient in the least restrictive manner? Is there evidence that the rights of the patient were protected while in the restrictive setting in accordance with Federal and State law and accepted standards of practice?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(d) Standard: Recording Progress	
B126	Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in '482.12(c),	§482.61(d) GUIDANCE: Refer to '482.61(c)(2) GUIDANCE for clarification between treatment notes and progress notes. The recording of progress is evidence of individual patient performance. Specifically, the progress notes recorded by the professional staff, or others responsible for the patient's treatment, must give a chronological picture of the patient's progress or lack of progress towards attaining short and long range goals outlined in the individual treatment plan. Progress notes should relate to the goals of the treatment plan. Notes that state, "patient slept well" or "no complaints" constitute observations and do not indicate how the patient is responding to treatment and progressing towards set goals. Frequency alone does not determine the adequacy of progress notes. Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind. Notes should be dated and signed (signature and title or discipline). §482.61(d) PROBES: Are the physicians who are significantly involved in active treatment modalities/interventions actually documenting progress? Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress? Is there a correlation between what is observed by the surveyor and what is described in the notes? Do the notes give a clear picture of the patient's progress or lack thereof, during the course of hospitalization? In reviewing the patient's progress, are aftercare/discharge plans being evaluated?
B127	nurse,	§482.61(d) PROBES: Are the nurses who are significantly involved in active treatment modalities/interventions actually documenting progress?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B128	social worker	§482.61(d) PROBES: Are the social workers who are significantly involved in active treatment modalities/interventions plan actually documenting progress?
B129	when appropriate, others significantly involved in active treatment modalities.	§482.61(d) PROBES: Are staff from other disciplines, i.e., rehabilitative therapy and psychology, who are significantly involved in active treatment modalities/interventions actually documenting progress?
B130	The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter,	§482.61(d) PROBES: What is the frequency of progress notes in relation to the condition of the patient?
	and must contain	
B131	recommendations for revisions in the treatment plan as indicated	§482.61(d) PROBES: Do the progress notes contain documentation substantiating changes/revisions in the treatment plan and subsequent assessment of the patient's responses and progress
	as well as	
B132	a precise assessment of the patient's progress in accordance with the original or revised treatment plan.	§482.61(d) PROBES: Do the notes give a clear picture of the patient's progress, or lack thereof, during the course of hospitalization? Are the progress notes related to the goals of the treatment plan?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(e)Standard: Discharge planning and discharge summary	
B133	The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization	§482.61(e) GUIDANCE: The record of each patient who has been discharged should indicate the extent to which goals established in the patient's treatment plan have been met. As part of discharge planning, staff consider the discharge alternatives addressed in the psychosocical assessment and the extent to which the goals in the treatment plan have been met. The surveyor should refer to hospital policy for discharge timeframes. The discharge summary should contain a recapitulation of the patient's hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan. This summary includes the reasons for admission, treatment achieved during hospitalization, a baseline of the psychiatric, physical and social functioning of the patient at the time of discharge, and evidence of thepatient/family response to the treatment interventions.
	and	
B134	recommendations from appropriate services concerning follow-up or aftercare	§482.61(e) GUIDANCE: The patient's discharge summary should describe the services and supports that are appropriate to the patient's needs and that will be effective on the day of discharge. Examples include: o A complete description of arrangements with treatment and other community resources for the provision of follow-up services. Reference should be made to prior verbal and written communication and exchange of information; o A plan outlining psychiatric, medical/physical treatment and the medication regimen as applicable;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		o Specific appointment date(s) and names and addresses of the service provider(s); o Description of community housing/living arrangement; o Economic/financial status or plan, i.e., supplemental security income benefits; o Recreational and leisure resources; and o A complete description of the involvement of family and significant others with the patient after discharge. §482.61(e) PROBES: How does the discharge planning process verify appointment source(s), dates and addresses? How was the patient involved in the discharge and aftercare planning process? Were discharge related documents made available to the patient, family, community treatment source and/or any other appropriate sources? Is there indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-hospital treatment entity? Is there evidence that contact with the post-hospital treatment entity included communication of treatment recommendations (including information regarding the patient's medications)? Is a contact person named, and does the patient have a specific appointment date and time for the initial follow-up visit?
	as well as	
B135	a brief summary of the patient's condition on discharge.	§482.61(e) GUIDANCE: The patient's discharge planning process should address anticipated problems after discharge and suggested means for intervention, i.e., accessibility and availability of community resources and support systems including transportation, special problems related to the patient's functional ability to participate in aftercare planning. The discharge summary and/or plan should contain information about the status of the patient on the day of discharge, including psychiatric, physical and functional condition.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B136	§482.62 Condition of Participation: Special staff requirements for psychiatric hospitals. The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.	§482.62 GUIDANCE: The purpose of this Condition of Participation is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients. Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, patient and staff injury reports, for indications that staffing is an issue. Adequate numbers are defined to mean the numbers, and deployment, of staff with qualifications to evaluate, plan, implement and document active treatment. Do not look at numbers alone. The hospital is responsible for organizing its available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment and patient assignments to wards and groups in such a way that results in patients achieving the maximum therapeutic benefit. §482.62 SURVEY PROCEDURE: Assess the adequacy of the Special Staffing Condition by: 1- Observing sampled patients and others during structured sessions and in unstructured settings. You should be able to observe behavioral evidence of a rational organization of resources. 2- Next, interview patients and staff to determine whether or not necessary treatment modalities and other services are being provided in a timely manner. 3- Next review the medical records of patients in the sample to ascertain if necessary active treatment assessments, treatments, evaluations and activities have been conducted and documented. 4- Also, review other records such as restraint and seclusion records, incident reports, medication error reports, reports of patient/staff injuries, etc., to determine the extent to which staffing levels or deployment contributed to negative patient outcomes. 5- Evaluate all outcome data in light of the success or failure observed during the survey relevant to each patient receiving active treatment, and achieving desired outcomes of care. This is the primary basis for evaluating the adequacy of the hospital's staffing under this Special Condition.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(a) Standard: Personnel.	
	The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:	
B137	(1)Evaluate patients;	§482.62 (a) (1) PROBES: Is there adequate staff to assure that the admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner? Is there evidence that there is continuing evaluation of the patient's progress and response to treatment? Are evaluations delayed or absent?
B138	(2)Formulate written individualized, comprehensive treatment plans;	§482.62(a)(2) GUIDANCE: Staffing must be sufficient so that members of the patient's treatment team and others responsible for evaluation and assessment can contribute their respective data for consideration in the formulation of the treatment plan. §482.62(a)(2) PROBES: Was there sufficient discipline participation at the treatment team meeting to assure formulation of a treatment plan that meets the patient's individualized needs? What problems prevent staff members from attending treatment meetings? Do they relate to staffing? Are the assessments/evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment?

TAG NUMBER	RESOLUTION	GUIDANCE TO SURVEYORS
B139	(3)Provide active treatment measures;	§482.62(a)(3) GUIDANCE: Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Although the active treatment process must be identifiable in documentation, it must be first and foremost observable and evident in daily practice. Treatment interventions need to be individualized, in that the patient receives assistance with resolving or ameliorating the problems/circumstances that led to hospitalization. Expect to see treatment focused on the unique needs of individual patients. For example, several patients may be referred to "Anger Management Group", but the focus of discussion and therapeutic intervention may differ depending on the individual patient's particular issue regarding managing anger. Whether structure must be imposed by staff or whether the patient can direct his or her own activities for periods of time (without staff supervision), is based on the patient's ability to engage in constructive, appropriate behavior (without engaging in harm to self or others). Be certain that the patient's time on the unit is maximized toward the further development of appropriate desired outcomes, including but not limited to leisure and recreation. §482.62(a)(3) PROBES: Through observation, interviews and record reviews, can you determine that patients receive active treatment? Is the distribution of staff consistent with particular patient needs? Is there sufficient appropriate staffing to carry out treatment plans? Does the patient attend therapies that are relevant to the identified problems that brought the patient to the hospital? Are staff absences and/or vacancies preventing the patient from receiving active treatment? Are patients not attending therapeutic activities off the unit because there are no staff to escort them? Are therapeutic groups not available on the unit for patients who are not able to go off the unit?

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		Are patients observed not engaged in activities while staff attend to administrative tasks? Are active treatment sessions or activities carried out at discrete time intervals exclusively? Or is active treatment implemented as the patient's needs emerge during the course of the day, as well? Does a review of quality assurance data reveal a pattern of serious incidents occurring on particular shifts and/or days of the week? What do patients report to the surveyor are their treatment modalities? Do patient interviews indicate that patients believe the treatment being provided is helpful? Does the scheduling of activities and their content relate directly to the patient's treatment objectives or are the activities/content generalized, non-therapeutic "time-fillers"? Can staff describe how their activities relate to the patient's treatment objectives? At any point in time, in any of the patient's experiences in the hospital is the thrust of the patient's treatment plan observable during the staff and/or patient interactions? Is there a consistent, observable pattern of evidence that hospital staff provide, reinforce and otherwise implement measures to achieve active treatment objectives?
B140	(4) Engage in discharge planning.	§482.62(a)(4) GUIDANCE: The patient together with all relevant professionals caring for the patient should be expected to participate in the discharge planning process. Staffing should be sufficient to facilitate this outcome, to the maximum extent possible. §482.62(a)(4) PROBES: Do patients participate in their discharge planning process? If not, why? Do staff interviews elicit information that staff working with patients are aware of the discharge plans for those patients? Do record review and interviews indicate that all relevant staff have participated in discharge planning?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(b) Standard: Director of inpatient psychiatric services; medical staff	
B141	Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.	§482.62(b) GUIDANCE: Inpatient psychiatric services include the following functions: admission interviews, assessments and evaluations; psychiatric and medical work-ups; treatment team leadership; medication management; on-call provision of emergency psychiatric and medical treatment; provision of individual, group and family therapies; provision of clinical supervision to other professionals and paraprofessionals; provision of medical and psychiatric educational workshops and conferences for all staff; and provision of consultation to staff for clinical and/or administrative matters. The clinical director is ultimately responsible for the medical and psychiatric care that is provided to patients. The clinical director should ascertain that quality improvement programs are in place to monitor all areas of patient care, and should implement educational programs for all levels of staff. §482.62(b) SURVEY PROCEDURE: Just prior to the end of the survey, schedule a meeting with the clinical director. By the time of this meeting, you should already have conducted required observation, interviews and record reviews for at least a majority of the patients in the sample. Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the clinical director; the leadership exhibited for the scope of psychiatric/medical treatment programs needed by patients; and the rationale for medical staffing coverage. If necessary, follow-up on letters of complaint previously reported serious problems, discrepancies with Data Collection Medical Staff Coverage (HCFA-729).
B142	The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.	§482.62(b) GUIDANCE: The number of full-time, part-time and consulting staff, who are board certified within each category and their availability to the hospital must be adequate to provide psychiatric services, as described above. Adequacy is considered in light of the following:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		1. Number of admissions, discharges and current patients by treatment units; 2. Size of the hospital; 3. Geographic proximity of the wards and units; 4. Organization and kinds of treatment services rendered to the patients; 5. Availability of the physician coverage on evening, nights and weekends; 6. Availability of physicians to participate in treatment planning; 7. Availability of psychiatrists to consult with non-psychiatric physicians about psychotropic medication regimens; and 8. Availability of physicians to consult with multi-disciplinary staff about treatment issues. §482.62(b) PROBES: How many staff are board certified? Fully trained? How many full-time/part-time specialties are represented? How are medical staff deployed? To what programs/units are they assigned? Why? How much time do physicians spend on the units? Based on observations, interviews, and medical record reviews is coverage adequate to meet the needs of sampled patients? To meet the needs of other patients observed during the survey?
B143	(1) The clinical director, service chief or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.	§482.62(b)(1) GUIDANCE: A physician is qualified to take the examinations for board certification upon successful completion of a psychiatric residency program approved by either the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology. '§482.62(b)(1) SURVEY PROCEDURES: Review the clinical director's personnel folder or ask the clinical director if he/she has one of the following: a. Certification of the American Board of Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry. b. If no certification, evidence that the person took the Boards would satisfy that the person had the training and equivalency to be admitted to the board examination. c. If indicated, medical school and residency training d. Length of time he has been employed at the facility; length of time he has been at his position.

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		To be admitted to the American Board Examinations the following conditions must be met: 1. License without restrictions. 2. Graduation from a medical school approved by either the Medical Osteopathic Association or the American Medical Association. 3. A successful completion of an approved residency training program for at least three years before 1988 which is approved by the America Council on Graduate Medical Education (ACGME). After 1988, it has to be a four year accredited program.
B144	(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.	§482.62(b)(2) GUIDANCE: Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice. In states which allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient's treatment. 482.62 (b) (2) PROBES: What mechanisms does the director use to monitor and evaluate the work of the medical staff (personal interviews? Quality Improvement reports? incident reports?)? When problems are discovered by the clinical director, how are they corrected? Are services, notes, and reports timely? Are medications used appropriately for the patient's diagnosis?
	(c) Standard: Availability of medical personnel.	
B145	Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the institution, the institution must	§482.62(c) GUIDANCE: Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients. Review the medical and surgical services provided by the hospital during the interview with the clinical director. Discuss contract or arrangements with the clinical director for services provided off grounds.

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	have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.	§482.62(c) PROBES: How did the hospital meet the medical/surgical/diagnostic needs represented by each patient in the sample? Were these done timely? Appropriately? If contracts are not current or available, how are these services provided for the patient, if needed? Is there evidence of negative outcomes as a result of these arrangements? Are reports from other services such as pharmacy, radiology, clinical laboratory timely? Appropriate?
	(d) Standard: Nursing services.	
B146	The hospital or unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.	§482.62(d) GUIDANCE: Psychiatric nursing functions may include the following: supervision of paraprofessional staff; assessment, planning, provision, and evaluation of psychiatric nursing care to patients; medication teaching; management of the therapeutic milieu; provision of mandatory and voluntary inservice training to all staff; and provision of specialized treatments and therapies, such as individual, group and family therapies, that require the clinical expertise of a professional psychiatric nurse. Expect to see evidence of orientation programs as well as ongoing continuing education programs for Licensed Practical Nurses and mental health workers that stress individualized treatment interventions. Determine that there is a qualified Director of Nursing (DON) providing the required leadership and supervision for the psychiatric nursing department.
B147	(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill.	§482.62(d)(1) GUIDANCE: During the interview with the DON, assess his/her educational background and psychiatric nursing and leadership skills. If the DON has less than a Master's Degree in Psychiatric Nursing, expect to see evidence of experience and on-going training in psychiatric nursing. Documented consultation from a nurse with a Master's in Psychiatric Nursing constitutes on-going training.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B148	The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.	§482.62(d)(1) GUIDANCE: Based on structured observations of the patients in the sample and other patients in the hospital, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice Information obtained from the DON should include: implementation of continuous quality improvement programs; provision of orientation, inservice and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention and management of violence, CPR and Universal Precautions. §482.62(d)(1) PROBES: Are nursing assessments completed on all patients? Do the multidisciplinary treatment plans reflect nursing input which include specific nursing interventions for nursing problems (e.g. violence toward self/others, physical/medical crises)? Is nursing care evaluated by an R.N., with changes in the care based on the patient's progress or lack thereof? Are intrusive techniques (e.g. seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g. medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with hospital policy, State statutes and safe nursing practice? Are nursing personnel observed relating to patients in a therapeutic manner?
B149	(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B150	There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.	§482.62(d)(2) GUIDANCE: The evaluation of sufficient numbers and level of R.N.'s, L.P.N.'s and mental health workers is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the hospital, patient interviews, and as evidenced in medical records and other data related to patients (e.g. incident reports, seclusion/restraint reports). Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care. There should be evidence that all nursing personnel have education, experience and/or training in psychiatric care. Mental health workers spend the majority of their work day interacting with patients. Expect to see evidence that they are receiving on-going supervision and training. Mental health workers should be assigned patient care duties and therapeutic modalities that reflect their educational level, psychiatric training, and experience. §482.62(d)(2) SURVEY PROCEDURE: The nursing staffing patterns should be reviewed on a sample of approximately 25% of the certified wards. The staffing, including levels of nursing personnel, should be reviewed for the day(s) of the survey and evaluated based on the level of needs presented by the patients. Additional staffing patterns shall be reviewed if a problem or concern is evidenced. Decisions regarding extent of additional data (number of wards and dates) to be reviewed shall be based on the degree of problem/concern. Patient need assessment/patient acuity shall be reviewed for any wards as deemed necessary based on problems/concerns found in the sampling review. If your observations and/or interviews indicate a staffing problem, you may want to consider the following variables in assessing adequacy of nursing personnel coverage: 1. Organization and types of services provided to patients by the nursing department. 2. Number and levels of nursing care needs of patients, including average length of stay, acuity of patients and nursing care requirements; 3. Number and levels of nursing personnel based on the roles and functions required of nursing; 4. Number of suicidal/assaultive patients; 5. Seclusion/restraint incidents;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		6. Number of admissions and discharges; 7. Number and type of accidents and/or injuries; 8. Amount and complexity of medication regimens; 9. Medication errors; 10. Use of P.R.N. (as needed) medications; 11. Medical (physical) procedures; 12. Assignment and utilization of "pool" nursing personnel (those staff who are hired through a contract service and are not employees of the hospital). Contractual staff should receive orientation and training necessary for assigned functions, and should be supervised by employees of the hospital; 13. Availability of R.N.'s to supervise/consult with nursing/non-nursing personnel about patient care; 14. Availability of R.N.s to assess and implement care in crisis situations; 15. Availability of R.N.'s to interact with patients in structured activities; and 16. Involvement of patients with personnel. §482.62(d)(2) PROBES: Are personnel interacting with patients? Are patients involved in structured activities? Are patients lying in beds/on floors, sitting alone, fighting and arguing? When interviewing/observing staff, do they interact therapeutically with patients? If unclear, request rationale from staff. Why have nursing staff been deployed in the manner that they have?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(e) Standard: Psychological services.	
B151	The hospital must provide or have available psychological services to meet the needs of the patients.	§482.62(e) GUIDANCE: Psychology services may include the following: diagnostic testing and diagnostic formulations on request from physicians; provision of individual, group and family therapies; participation in multi-disciplinary treatment conferences; and program development and evaluation. The number of full-time, part-time and consulting psychologists must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided. §482.62(e) PROBES: Did the patients in the sample have a need for psychological services or testing? Were they provided in a timely manner and with sufficient intensity? Did any of the patients in the sample indicate a need for psychological services, but none were requested? What types of psychological services are offered? (e.g., assessments, therapy) Do certain groups of patients receive testing routinely? Dementia?, Children?, Adolescents? Why? Once tests are performed, are results reported in sufficient time to be integrated in the patient's active treatment and treatment plan? How does the hospital or Psychological Service Department determine whether or not: it meets the needs of patients? its services are underutilized or overutilized? Why have psychological services staff been deployed in the manner that they have?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS	
		TAG NUMBER	REGULATIO
B153	The services must be furnished in accordance with accepted standards of practice and established policies and procedures.		(f) Standard: Soci
		B152	There must be a dir appropriateness of s

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B154	(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree in social work, at least one staff member must have this qualification.	§482.62(f)(1) GUIDANCE: The duties, functions, and responsibilities of the director of social services/social work should be clearly delineated and documented in the facility's policies and procedures. If the director is not MSW qualified and at least one staff member is MSW qualified, verify the duties, functions, and responsibilities of the MSW. §482.62(f)(1) PROBES: What are the director's qualifications, experience and scope of duties within this position? If a MSW staff member, other than the director, is performing any of these duties, what are this staff member's experience and scope of duties performed? Why were these duties delegated? To what extent is the director's knowledge of the social work needs of the various wards? Why has the social work staff and services provided throughout the hospital been deployed in the manner it has?
B155	(2) Social service staff responsibilities must include, but are not limited to, participating in discharge, planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.	§482.62(f)(2) GUIDANCE: Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission. High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated. The anticipated social work role and expected interventions as recommended in the psychosocial assessment should be considered by the treatment team for possible inclusion into the patient's treatment plan. Treatment and discharge planning activities, liaison/follow-up efforts should be based upon the goals, including discharge goals, and staff responsibilities specified in the treatment plan. §482.62(f)(2) PROBES: Are social work staff routinely involved in providing services to the patient that are identified in the treatment plan?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		To what extent do social work staff provide discharge planning services to the patient in the way of: supportive individual, couple, family, or group therapy focused on discharge goals of the patient? carrying out a liaison role with community resource providers? Have social work staff assured that adequate information is provided to post-hospital patient service providers?
	(g) Standard: Therapeutic activities.	
B156	The hospital must provide a therapeutic activities program.	§482.62(g) GUIDANCE: A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patients. Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient's functioning. In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences. A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients the priority need may be for leisure education and activities.
B157	(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.	§482.62(g)(1) GUIDANCE: The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs. The selection of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling. There are other disciplines that also serve paients. Consultants include but are not limited to the following: educational instructors, registered occupational therapist/certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and registered physical therapist. The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or the work adjustment specialist.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
B158	(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.	§482.62(g)(2) GUIDANCE: Qualified staff should complete their respective discipline assessments for use in multidisciplinary treatment planning. Specific role(s) and modalities to be implemented by rehabilitative staff must be determined by goals set in the patient's treatment plan. Qualified therapists who provide clinical services and administrative staff should utilize established monitoring and evaluation mechanisms to conduct consistent timely review of the quality and appropriateness of therapeutic and rehabilitative services delivered to patients. §482.62(g)(2) PROBES: Is there evidence that sampled patients and staff are familiar with the goals and staff interventions described in the patient's treatment plan? Are these interventions observed being carried out? What is the patient's response? Are these interventions and activities of sufficient frequency and intensity to achieve maximum therapeutic benefit? What are the qualifications, experience, duties and responsibilities of the Therapeutic Activities Director and discipline supervisor(s)? How is the program organized? Did the patients in the sample have a need for any therapeutic activities? Were their needs met? Did any of the patients in the sample indicate a need for therapeutic activities, but none were considered? What kinds of services are provided to the patient population? Are activity areas/sites accessible and available to meet the patient's individual needs? Are the facilities and resources adequate to enable implementation of goals set in the patient's treatment plan?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	-	Does the program utilize available community resources to provide opportunities for socialization, leisure, and therapeutic and/or rehabilitation activities for patients who can participate outside the hospital setting? Are current activity schedules clearly posted for patient and staff reference and use? Are the scheduled activities related to the particular patient area and specific treatment needs of patients? Are patient needs met consistently at all times including evenings and weekends? If a large number of patients are assigned to the same therapeutic activity, do patient's have individualized goals within their treatment plans? Why have therapeutic activities staff been deployed in the manner they have?

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